111-1120.00 DAPP-7

patent term

CERTIFICATION UNDER 37 C.F.R. 1.10

EM322714832US
"Express Mail" Mailing Number

February 6, 1998
Date of Deposit

I hereby certify that this paper, fee and documents referred to herein is being deposited with the United States Postal Service "Express Mail Post Office to Addressee" service under 37 C.F.R. 1.10 on the date indicated above and is addressed to the Asst. Commissioner for Patents, U.S. Patent and Trademark Office, Box Patent Ext., Washington, D.C. 20231.

Cederic Rodgers
Name of Person Mailing Application

Cederic Rodgers
(Signature of Person Mailing Application)

TRANSMITTAL OF APPLICATION FOR EXTENSION OF THE TERM OF A PATENT

Assistant Commissioner for Patents
U.S. Patent and Trademark Office
Box Patent Ext.
Washington, D.C. 20231

07/365,154

In re Patent No. 5,105,808
Issued to: Robert S. Neuwirth and Lee R. Bolduc
Issue Date: April 21, 1992
For: INTRAUTERINE CAUTERIZING APPARATUS

Docket Ref: Gynelab808

Dear Sir:

We are transmitting herewith the attached:

X Application for Extension of the Term of a Patent (original and 4 certified* copies) including photocopies of:

- X Exhibit A-ThermaChoice™ Uterine Balloon Therapy System (1) Patient Information Brochure; (2) Catheter Instruction for Use; and (3) UBT System Operating Manual;
- X Exhibit B-Patent No. 5,105,808 issued to Neuwirth et al on April 21, 1992;
- X Exhibit C-Description of activities undertaken by licensee during the applicable regulatory period;
- X Exhibit D-Power of Attorney and Certificate under 37 CFR 3.73(b); and
- X Exhibit E-Authorization of the Pre-Marketing Approval Holder-Gynecare, Inc./Ethicon, Inc.

X *Rule 740(16) Certification of Duplicate of Application for Extension of the Term of a Patent (attached to 4 copies).

X Stamped return addressed postcard.

X A check in the amount of $1120.00 (Extension of Term of Patent-37 CFR 1.20(j)(1).

X Please charge any deficiency or credit any overpayment in fees to Deposit Account No. 15-0508. A duplicate of this transmittal is enclosed.

Date: February 6, 1998

By: Talivaldis Cepuritis
Reg. No. 20,818
OLSON & HIERL, LTD.
20 North Wacker Drive
36th Floor
Chicago, Illinois 60606
(312) 580-1180
Attorneys for Applicant

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CERTIFICATION UNDER 37 C.F.R. 1.10

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Date: February 6, 1998

By: Talivaldis Cepuritis
Talivaldis Cepuritis
Reg. No. 20,818
OLSON & HIERL, LTD.
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Chicago, Illinois 60606
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CERTIFICATION UNDER 37 C.F.R. 1.10

EM322[illegible]82US
"Express Mail" Mailing Number

February 6, 1998
Date of Deposit

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Cederic Rodgers
Name of Person Mailing Application

Cederic Rodgers
(Signature of Person Mailing Application)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Inventor: Robert S. Neuwirth and Lee R. Bolduc

Assignee: Gynelab Products, Inc.

Patent No.: 5,105,808

Licensee: Gynecare, Inc./Ethicon, Inc.

Issue Date: April 21, 1992

For: INTRAUTERINE CAUTERIZING APPARATUS

APPLICATION FOR EXTENSION OF THE TERM OF A PATENT

Assistant Commissioner for Patents
U.S. Patent and Trademark Office
Box Patent Ext.
Washington, D.C. 20231

Docket Ref.: Gynelab808

Dear Sir:

Pursuant to 35 U.S.C. §156, extension of the term of the above-identified United States patent is respectfully requested. Pursuant to the guidelines published by the Commissioner, the following information is being submitted.

(1) A complete identification of a method of using the approved ThermaChoice™ Uterine Balloon Therapy (UBT) System is set forth in attached collective Exhibit A in the photocopies of

the Patient Information Brochure (Exhibit A(1)); the Catheter Instructions for Use (Exhibit A(2)); and the UBT System Operating Manual (Exhibit A(3)) of owner's exclusive licensee, Gynecare, Inc./Ethicon, Inc. describing and illustrating the method.

(2) The regulatory review occurred under Title 21, United States Code, the Federal Food, Drug and Cosmetic Act, as amended 1976, §515(d)(1)(B)(ii) [21 U.S.C. §360e(d)(1)(B)(ii)] and §520(e) [21 U.S.C. §360j(e)].

(3) The method of using the approved product received permission for commercial use by owner's licensee, Gynecare, Inc./Ethicon, Inc. on December 12, 1997, under the provisions of the Federal Food, Drug and Cosmetic Act as administered by the Food and Drug Administration (FDA) under which the applicable regulatory review period occurred.

(4) This is not a human drug product, therefore no ingredients are described.

(5) This application is being submitted within the sixty day period permitted for submission, the date of the last day on which the application could be submitted being February 9, 1998.

(6) United States patent No. 5,105,808 is the patent for which an extension is being sought. The patent, which is set to expire on April 21, 2009, was issued to Robert S. Neuwirth and Lee R. Bolduc on April 21, 1992, and is owned by the applicant, Gynelab Products, Inc. The patent for which extension is being sought is a division of patent No. 4,949,718, issued to Robert S. Neuwirth and Lee R. Bolduc on August 21, 1990, owned by the applicant, Gynelab Products, Inc., and for which an application for extension of the term of the patent is concurrently being submitted.

(7) Enclosed as Exhibit B is a copy of patent No. 5,105,808 for which an extension is being sought.

(8) Patent No. 5,105,808 is the subject of the following two pending Reexaminations but no Reexamination Certificates have been issued:

a. Reexamination No. 90/004/458 filed November 12, 1996; and

b. Reexamination No. 90/004,718, filed September 30, 1997.

(9) Patent No. 5,105,808 claims the method of using the approved ThermaChoice™ Uterine Balloon Therapy (UBT) System. Claims 1-3 of Patent No. 5,105,808 and claims 1-3 as amended in Reexamination No. 90/004/458 are applicable to and read on the method of using the approved ThermaChoice™ Uterine Balloon (UBT) Therapy System as indicated below.

A. U.S. Patent No. 5,105,808

1. A method for effecting cauterization necrosis of the tissue lining of a mammalian body cavity comprising the steps of:	The method practiced with the UBT System ablates uterine tissue by thermal energy for effecting cauterization necrosis of the uterine endometrium, which is the tissue lining of a human female uterus. See Exhibit A(1) section "What is ThermaChoice™ Uterine Balloon Therapy?" describing how the method destroys the lining of the uterus with the use of heat; and pages 1 of both Exhibits A(2) and A(3), "Device Description" section.
(a) inserting a distendable bladder into the body cavity;	A distendable balloon bladder is inserted into the uterine body cavity. See the pictorial depiction of its insertion in the uterus in Exhibit A(1), section "How does ThermaChoice work?"; and the instructions in section 3 of Exhibit A(2), pages 9-10 and of Exhibit A(3), pages 10-11.
(b) inflating said distendable bladder to a predetermined pressure with a fluid so that said distendable bladder is in contact with substantially all	The balloon bladder is inflated under pressure to contact the uterine lining. See the pictorial depiction of the inflated balloon in

of the tissue lining for which necrosis is desired;	contact with the endometrium of the uterus in Exhibit A(1) section "How does ThermaChoice work?"; and section 3 of the instructions in Exhibit A(2), pages 9-10 and in Exhibit A(3), pages 10-11.
(c) heating said fluid by means of a heating element positioned internal to said distendable bladder;	The fluid in the balloon bladder is heated by a heater positioned within the balloon. See the description of the heated fluid in Exhibit A(1) section "How does ThermaChoice work?"; and the discussion of the heater's function in the diagrams on pages 2 and 8 of Exhibit A(2) and pages 2 and 9 of Exhibit A(3) and the method of activating the heater in the instructions on pages 10-11 of Exhibit A(2) and on pages 11-12 of Exhibit A(3).
(d) controlling the temperature and pressure of said fluid by control means connected to said distendable bladder; and	The temperature and pressure of the fluid is controlled by a controller (GC-EAS) connected to the balloon bladder unit (GC-EAC) and umbilical cable (GC-EAU). See the diagrams on pages 2 and 8 of Exhibit A(2) and pages 2 and 9 of Exhibit A(3) and the directions for use on pages 7-11 of Exhibit A(2) and on pages 8-12 of Exhibit A(3) describing the control, its connection and its function.
(e) maintaining the exterior of said bladder so inflated with said fluid at a temperature of about 190°F. to about 215°F. and preferably about 210°F. for a period of time of from about 4 to about 12 minutes, and preferably about 6 minutes to effect cauterization necrosis of substantially all of the tissue lining of the body	The exterior of the balloon bladder of the UBT System is maintained inflated and the temperature of the heated fluid in the balloon is maintained in the range of 87°C (188°F) to 90°C (194°F) for an 8 minute therapy treatment cycle time which is within the claimed period. See Exhibit A(1) section "How does ThermaChoice work?"; and section 4 of the instructions

cavity for which necrosis is desired.	for use in Exhibit A(2), pages 10-11 and in Exhibit A(3), pages 10-13 where the method of inflating the balloon and the operating parameters for maintaining the fluid in the inflated balloon heated during the therapy cycles are described.
2. A method for effecting cauterization necrosis of an uterine endometrium comprising the steps of:	The method practiced with the UBT System ablates uterine tissue by thermal energy for effecting cauterization necrosis of the uterine endometrium. See Exhibit A(1) section "What is ThermaChoice™ Uterine Balloon Therapy?" describing how the method destroys the lining of the uterus with the use of heat; and pages 1 of both Exhibits A(2) and A(3), "Device Description" section.
(a) inserting a distendable bladder into the uterus;	A distendable balloon bladder is inserted into the uterine body cavity. See the pictorial depiction of its insertion in the uterus in Exhibit A(1), section "How does ThermaChoice work?"; and the instructions in section 3 of Exhibit A(2), pages 9-10 and of Exhibit A(3), pages 10-11.
(b) inflating said distendable bladder to a predetermined pressure with a fluid so that said distendable bladder is in contact with substantially all of the endometrium;	The balloon bladder is inflated under pressure to contact the uterine endometrium. See the pictorial depiction of the inflated balloon in contact with the lining of the uterus in Exhibit A(1) section "How does ThermaChoice work?"; and section 3 of the instructions in Exhibit A(2), pages 9-10 and in Exhibit A(3), pages 10-11.

(c) heating said fluid by means of a heating element positioned internal to said distendable bladder;	The fluid in the balloon bladder is heated by a heater positioned within the balloon. See the description of the heated fluid in Exhibit A(1) section "How does ThermaChoice work?"; and the discussion of the heater's function in the diagrams on pages 2 and 8 of Exhibit A(2) and pages 2 and 9 of Exhibit A(3) and the method of activating the heater in the instructions on pages 10-11 of Exhibit A(2) and on pages 11-12 of Exhibit A(3).
(d) regulating the temperature and pressure of said fluid by control means connected to said distendable bladder; and	The temperature and pressure of the fluid is controlled by the controller (GC-EAS) connected to the balloon bladder. See the diagrams on pages 2 and 8 of Exhibit A(2) and pages 2 and 9 of Exhibit A(3) and the directions for use on pages 7-11 of Exhibit A(2) and on pages 8-12 of Exhibit A(3) describing the controller, its connection and its function.
(e) maintaining said bladder so inflated with said fluid at a temperature for a period of time sufficient to effect cauterization necrosis to substantially all of the uterine endometrium.	The balloon bladder of the UBT System is maintained inflated and the fluid within the balloon is maintained at a heated temperature during a therapy treatment cycle time for cauterizing necrosis of the uterine endometrium. See Exhibit A(1) section "How does ThermaChoice work?"; and section 4 of the instructions for use in Exhibit A(2), pages 10-11 and in Exhibit A(3), pages 10-13 where the method of inflating the balloon and the operating parameters for maintaining the fluid in the inflated balloon heated during the therapy cycle are described.

3. A method as described in claim 2, wherein the exterior of said distendable bladder in contact with the endometrium is maintained at a temperature of 190~[sic] to 215~[sic] F. and preferably about 210~[sic] F. for a period of time of from 4 to 12 minutes, and preferably about 6 minutes.	See discussion of claim 2 above and the description of how the exterior of the inflated balloon bladder contacts the uterine lining in the pictorial depiction of the inflated balloon in contact with the endometrium (lining) of the uterus in Exhibit A(1) section "How does ThermaChoice work?"; section 3 of the instructions in Exhibit A(2), pages 9-10 and in Exhibit A(3), pages 10-11; and the operating parameters for maintaining the temperature of the heated fluid in the range of 87°C (188°F) to 90°C (194°F) for an 8 minute therapy treatment cycle time which is within the claimed period.

B. <u>The pending amended claims in Reexam No. 90/004/458</u>

1. A method for effecting cauterization necrosis of uterine endometrium comprising the steps of:	The method practiced with the UBT System ablates uterine tissue by thermal energy for effecting cauterization necrosis of the uterine endometrium. See Exhibit A(1) section "What is ThermaChoice™ Uterine Balloon Therapy?" describing how the method destroys the lining of the uterus with the use of heat; and Exhibits A(2) and A(3), page 1, "Device Description" section.
(a) inserting a distendable bladder into the uterine cavity;	A distendable balloon bladder is inserted into the uterine body cavity. See the pictorial depiction of its insertion in the uterus in Exhibit A(1), section "How does ThermaChoice work?"; and the instructions in section 3 of Exhibit A(2), pages 9-10 and of Exhibit A(3), pages 10-11.

(b) inflating said distendable bladder to a predetermined pressure with a fluid so that said distendable bladder distends the uterus and is in contact with substantially all of the endometrium;	The balloon bladder is inflated to a predetermined pressure to contact the endometrium and thereby applies pressure against the uterine wall. See the pictorial depiction of the inflated balloon in contact with the lining of the uterus in Exhibit A(1) section "How does ThermaChoice work?"; and section 3 of the instructions in Exhibit A(2), pages 9-10 and in Exhibit A(3), pages 10-11.
(c) heating said fluid within the inserted and inflated bladder by means of a heating element positioned internal to said distendable bladder;	The fluid in the balloon bladder is heated by a heater positioned within the balloon. See the description of the heated fluid in Exhibit A(1) section "How does ThermaChoice work?"; the discussion of the heater's function in the diagrams on pages 2 and 8 of Exhibit A(2) and pages 2 and 9 of Exhibit A(3) and the method of activating the heater in the instructions on pages 10-11 of Exhibit A(2) and on pages 11-12 of Exhibit A(3).
(d) controlling the temperature and pressure of said fluid by control means connected to said distendable bladder; and	The temperature and pressure of the fluid is controlled by a controller (GC-EAS) connected to the balloon bladder unit (GC-EAC) and umbilical cable (GC-EAU). See the diagrams on pages 2 and 8 of Exhibit A(2) and pages 2 and 9 of Exhibit A(3) and the directions for use on pages 7-11 of Exhibit A(2) and on pages 8-12 of Exhibit A(3) describing the controller, its connection and its function.
(e) maintaining the exterior of said bladder so inflated with said fluid at a temperature of about 190°F. to about 215°F. and preferably	The exterior of the balloon bladder of the UBT System is maintained inflated and the temperature of the heated fluid in the balloon is

about 210°F. for a period of time of from about 4 to about 12 minutes, and preferably about 6 minutes to effect cauterization necrosis of substantially all of the endometrium.	maintained in the range of 87°C (188°F) to 90°C (194°F) for an 8 minute therapy treatment cycle time which is within the period claimed. See Exhibit A(1) section "How does ThermaChoice work?"; and section 4 of the instructions for use in Exhibit A(2), pages 10-11 and in Exhibit A(3), pages 10-13 where the method of inflating the balloon and the operating parameters for maintaining the fluid in the inflated balloon heated during the therapy cycles are described.
2. A method for effecting cauterization necrosis of an uterine endometrium comprising the steps of:	The method practiced with the UBT System ablates uterine tissue by thermal energy for effecting cauterization necrosis of the uterine endometrium, which is a tissue lining in a human female body cavity. See Exhibit A(1) section "What is ThermaChoice™ Uterine Balloon Therapy describing how the method destroys the lining of the uterus with the use of heat; and Exhibits A(2) and A(3), page 1, "Device Description" section.
(a) inserting a distendable bladder into the uterus;	A distendable balloon (bladder) is inserted into the uterine body cavity. See the pictorial depiction of its insertion in the uterus in Exhibit A(1), section "How does ThermaChoice work?"; and the instructions in section 3 of Exhibit A(2), pages 9-10 and of Exhibit A(3), pages 10-11.
(b) inflating said distendable bladder to a predetermined pressure with a fluid so that said distendable bladder	The balloon bladder is inflated to a predetermined pressure to contact the uterine lining which applies

distends the uterus and is in contact with substantially all of the endometrium;	pressure against the uterine wall. See the pictorial depiction of the inflated balloon in contact with the endometrium of the uterus in Exhibit A(1) section "How does ThermaChoice work?"; and section 3 of the instructions in Exhibit A(2), pages 9-10 and in Exhibit A(3), pages 10-11.
(c) heating said fluid within the inserted and inflated bladder by means of a heating element positioned internal to said distendable bladder;	The fluid in the balloon bladder is heated by a heater positioned within the balloon. See the description of the heated fluid in Exhibit A(1) section "How does ThermaChoice work?"; and the discussion of the heater's function in the diagrams on pages 2 and 8 of Exhibit A(2) and pages 2 and 9 of Exhibit A(3) and the method of activating the heater in the instructions on pages 10-11 of Exhibit A(2) and on pages 11-12 of Exhibit A(3).
(d) regulating the temperature and pressure of said fluid by control means connected to said distendable bladder; and	The temperature and pressure of the fluid is controlled by the controller (GC-EAS) connected to the balloon bladder. See the diagrams on pages 2 and 8 of Exhibit A(2) and pages 2 and 9 of Exhibit A(3) and the directions for use on pages 7-11 of Exhibit A(2) and on pages 8-12 of Exhibit A(3) describing the controller, its connection and its function.
(e) maintaining said bladder so inflated with said fluid at a temperature for a period of time sufficient to effect cauterization necrosis to substantially all of the uterine endometrium.	The balloon bladder of the UBT System is maintained inflated and the fluid within the balloon is maintained at a heated temperature during a therapy treatment cycle time for cauterizing necrosis of the uterine endometrium. See Exhibit A(1) section "How does ThermaChoice work?"; and

	section 4 of the instructions for use in Exhibit A(2), pages 10-11 and in Exhibit A(3), pages 10-13 where the method of inflating the balloon and the operating parameters for maintaining the fluid in the inflated balloon heated during the therapy cycle are described.
3. A method as described in claim 2, wherein the exterior of said distendable bladder in contact with the endometrium is maintained at a temperature of 190° F. to 215° F. and preferably about 210° F. for a period of time of from 4 to 12 minutes, and preferably about 6 minutes.	See discussion of claim 2 above and the description of how the exterior of the inflated balloon bladder contacts the uterine lining in the pictorial depiction of the inflated balloon in contact with the endometrium (lining) of the uterus in Exhibit A(1) section "How does ThermaChoice work?"; section 3 of the instructions in Exhibit A(2), pages 9-10 and in Exhibit A(3), pages 10-11; and the operating parameters for maintaining the temperature of the heated fluid in the range of 87°C (188°F) to 90°C (194°F) for an 8 minute therapy treatment cycle time which is within the claimed period.

(10) The relevant dates and information necessary in order to enable the Secretary of Health and Human Services to determine the applicable regulatory review period pursuant to 35 U.S.C. §156(g) are set forth as follows, references being made to 35 U.S.C. §156(g)(3)(B):

i. Effective date of IDE No. G940155: November 30, 1994.

ii. Clinical investigation on humans first begun: January 2, 1996.

iii. Premarket approval application initially submitted: June 16, 1997.

iii. PMA No. P970021 granted: December 12, 1997.

All additional relevant dates are set forth in attached Exhibit C.

(11) A brief description of the activities undertaken by the exclusive licensee of applicant during the applicable regulatory review period with respect to the approved product and the significant dates applicable to such activities is set forth in attached Exhibit C.

A description of the clinical use of the ThermaChoice™ Uterine Balloon Therapy System is set forth in Exhibit A(2), pages 4-7 and Exhibit A(3), pages 6-8.

(12) In the opinion of the applicant, the patent is eligible for the extension until July 11, 2010.

The 446 day term of extension is computed in accordance with 37 CFR §1.777(d)(2). This date is earlier than the term extension computed by adding 14 years to the date of approval of the premarketing application (i.e., calculated from December 12, 1997) under 37 CFR §1.777(d)(3) or the five year maximum period added to the original expiration date of the patent, i.e., (calculated as 17 years from issuance date of April 21, 1992) under 37 CFR §1.777(d)(5)(i).

(13) Applicant acknowledges a duty to disclose to the Commissioner of Patents and Trademarks and the Secretary of Health and Human Services any information which is material to the determination of entitlement to the extension sought.

(14) The prescribed fee under 37 CFR 1.20(j)(1) for receiving and acting upon the application for extension in the amount of $1,120.00 is concurrently enclosed.

(15) All inquiries and correspondence relating to the application for patent term extension are to be directed to the undersigned pursuant to:

a. Power of Attorney from Gynelab Products, Inc., the Owner Applicant, to Talivaldis Cepuritis et al, to prosecute this application and Assignee Certification under 37 CFR §3.73 attached as Exhibit D; and

b. Authorization of the Pre-Marketing Approval Holder, Gynecare, Inc./Ethicon, Inc., the exclusive licensee of Gynelab Products, Inc. attached as Exhibit E. Gynecare, Inc. was acquired by Ethicon, Inc. in November, 1997 and is a wholly owned subsidiary of Ethicon, Inc.

(16) A duplicate of the application papers (including Exhibits), certified as such, is submitted herewith in quadruplicate.

The undersigned declares that he:

1. is a patent attorney authorized to practice before the Patent and Trademark Office and has a power of attorney, submitted herewith as Exhibit D, authorizing him to act on behalf of the Owner Applicant in patent matters;

2. has reviewed and understands the contents of this application being submitted pursuant to 37 CFR §1.740;

3. believes Patent No. 5,105,808 is subject to extension pursuant to 37 CFR §1.710, because it claims a method of using a medical device subject to regulation under the Federal Food, Drug and Cosmetic Act;

4. believes an extension of the length claimed is fully justified under 35 U.S.C. §156 and the applicable regulations; and

5. believes the patent for which the extension is being sought meets the conditions for extension of the term of a patent as set forth in 37 CFR §1.720 because:

   a. the patent claims a method of using an Intrauterine Cauterizing Apparatus which is a medical device subject to regulation under the Federal Food, Drug, and Cosmetic Act;

   b. the term of the patent has never been previously extended;

   c. this application for extension is being appropriately submitted pursuant to the Rules;

   d. the approved product used for practicing the claimed method has been subjected to a regulatory review period as defined in 35 U.S.C. §156(g) and by the Secretary of Health and Human Services before its commercial marketing or use;

   e. the approved product used for practicing the claimed method has received permission for commercial marketing or use and the application is being submitted within the sixty day period beginning on the date the product first received

permission for commercial marketing under the provision of law under which the applicable regulatory review period occurred;

f. the term of the patent has not expired before the submission of this application; and

g. no other patent has been extended for the same regulatory review period for the product.

The undersigned hereby declares further that all statements made herein of his own knowledge are true and that all statements made upon information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any extension of patent term issuing thereon.

Respectfully submitted,

Date: February 6, 1998

By: /Talivaldis Cepuritis/
Talivaldis Cepuritis
Reg. No. 20,818

OLSON & HIERL, LTD.
20 North Wacker Drive
36th Floor
Chicago, Illinois 60606
(312) 580-1180
Attorneys for Applicant

What other treatments are available for me?

Drug therapy (such as low dose birth control pill or other hormones) is frequently prescribed for excessive bleeding caused by hormonal imbalance. It is often used among women who wish to retain fertility and can be effective in decreasing bleeding without the need for surgery. Repeated, long term dosing is usually required. Minor side effects are common and may include headache, breast tenderness, and weight gain. Major complications are rare.

Dilation and curettage (D&C) is typically the first surgical step if drug therapy fails. The top layer of the uterine lining is scraped away which may reduce bleeding, usually for only a few cycles. D&C is typically performed in an outpatient surgery setting under general anesthesia. If a polyp (small overgrowth) is removed, the problem may be corrected.

Hysteroscopic endometrial ablation destroys and removes the uterine lining with an electrosurgical instrument or laser. The procedure may be performed under general or regional anesthesia, and involves an instrument used to view the uterus (hysteroscope), and a heat source which is inserted through the hysteroscope into the uterus. The procedure is typically performed in 30-60 minutes. Most women return to work in two to three days. This method will reduce heavy bleeding approximately 85% of the time, with light or normal reduction in some patients and elimination of bleeding in others. Risks may include accidental uterus perforation, bleeding, infection, or heart failure due to the quantity of fluids used during the procedure.

Hysterectomy (removal of the uterus) provides a cure for excessive bleeding. It is major surgery which is usually performed under general anesthesia. Several days in the hospital and up to six weeks recovery are most common.

Talk with your doctor...understand all your options.

THERMACHOICE™

Uterine Balloon Therapy

A new minimally invasive choice for you and your doctor to consider in the treatment of excessive menstrual bleeding, ThermaChoice has the potential to offer:

- An alternative to hysterectomy or other major surgical procedures
- An outpatient procedure; no hospital stay
- Less need for general anesthesia
- A fast recovery, with a return to normal activity within two days for most patients
- Reduced bleeding

Talk with your doctor if you have specific questions about ThermaChoice and about your options to treat excessive bleeding.

GYNECARE

Ethicon, Inc.
A Johnson & Johnson Company

235 Constitution Drive
Menlo Park, CA 94025 USA
Telephone: 650-614-2500
Fax: 650-462-6742

PN00730 Rev.8

Excessive Menstrual Bleeding

You Don't Have to Live With It Anymore!

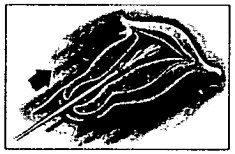
THERMACHOICE™
Uterine Balloon Therapy™

What is ThermaChoice™ Uterine Balloon Therapy™? It is a new outpatient procedure to reduce excessive menstrual bleeding. Unlike hysterectomy, which takes out the entire uterus, the procedure just destroys the lining of the uterus by the use of heat.

What can I expect from ThermaChoice? In most cases, bleeding during your period will be reduced to moderate or light flow. Some women may experience spotting; a few may experience no bleeding at all. Clinical data has shown that up to 15% of patients may not respond to ThermaChoice therapy and may require additional treatment.

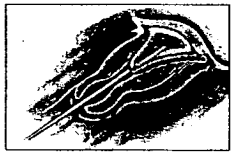
Am I a candidate for ThermaChoice? Your doctor must rule out abnormal uterine conditions like some fibroids, and your pap smear and biopsy must also be normal. This is not a treatment for uterine cancer. **If you still want to have children, ThermaChoice is not an option since the uterine lining is destroyed during therapy.**

How does ThermaChoice work?



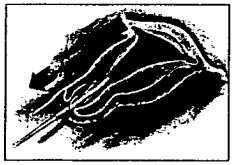
First, a soft flexible balloon attached to a thin catheter (tube) is inserted into the vagina, through the cervix and placed gently into the uterus.

Then the balloon is inflated with a sterile fluid which expands to fit the size and shape of your uterus.



The fluid in the balloon is heated to 87° C (degrees) or 188° F and maintained for eight minutes while the uterine lining is treated.

When the treatment cycle is complete, all the fluid is withdrawn from the balloon and the catheter is removed. Nothing stays in your uterus.



Your uterine lining has been treated and will slough off like a period in the next 7-10 days.

A New Treatment Alternative

Can I get pregnant after treatment? This therapy should not be used if you ever want to have children — in fact, pregnancies after ablation can be **dangerous for both fetus and mother.** Since there is a chance pregnancy could occur, contraception or sterilization should be used after treatment. Please discuss these options with your physician.

What will I feel during the procedure? About an hour before therapy, your physician may give you medication which minimizes cramping during and after the procedure. You may also be given a mild sedative to help you relax. In most cases, you will be awake during the procedure and may experience cramping and/or discomfort. Your doctor may use a local anesthesia to numb the cervix and the uterus. Sometimes patients want to be "put to sleep" using general anesthesia after which you may experience some nausea. This is an option for you to discuss with your doctor.

What will I feel after the procedure? You may feel mild or moderate cramping like a menstrual period, and if needed, your doctor will give you a mild medication to make you more comfortable. After 1-4 hours in the recovery room, you should arrange to be driven home where you can take it easy for the rest of the day.

What can I expect after I go home? Most women can return to work and family commitments by the next day. Sexual activity can be resumed after your first check-up, usually 7-10 days. Most patients have a pinkish and watery vaginal discharge for about 2 weeks, sometimes as long as a month. In some cases, the first few periods after the procedure may continue to be heavy but will begin to improve thereafter.

Are there any post-procedure complications for which I should call my physician after I get home? You should call your physician if you develop a fever of 100.4° Fahrenheit or over, worsening pelvic pain that is not relieved by ibuprofin (e.g. Motrin or Advil) or other medication prescribed by your physician, nausea, vomiting, bowel or bladder problems, and/or a greenish vaginal discharge.

What are the risks of ThermaChoice? The procedure may pose some rare, but possible, safety risks including blood loss, heat burn of internal organs, electrical burn, perforation (hole) or rupture of the wall of the uterus, or leakage of heated fluid from the balloon into the cervix or vagina. Collection of blood or tissue in the uterus and/or fallopian tubes during the months post-procedure is also possible and may require an outpatient procedure to correct the problem.

As with any type of uterine procedure, there may also be the risk of infection, usually easily managed with oral antibiotic therapy.

Caution: This product contains natural rubber latex which may cause allergic reactions.

What you should know about excessive menstrual bleeding

I bleed so heavily every month, I can't leave home. Is this normal? Heavy bleeding is not normal, but it is common. One out of every 5 women has unusually **heavy bleeding**, also called **menorrhagia.** Women just like you have described symptoms of unmanageable bleeding, flooding, clotting and a constant need to change pads or tampons which quickly become soaked. You feel tired, worry about embarrassing accidents and are frustrated when your periods rule your life.

What causes menorrhagia? The most common cause is hormonal imbalance, especially in women 35-45, prior to menopause. Benign (non-cancerous), uterine growths, such as fibroids or polyps, infection, or chronic illness can also cause excessive bleeding.

How is excessive bleeding evaluated? In order to find the cause of bleeding and determine the right treatment for you, your doctor will take a thorough history and may perform tests which provide information about the lining of your uterus. Talk to your doctor about which tests are appropriate for your specific needs.

Gynecare™

THERMACHOICE™

Uterine Balloon Therapy

Thermal Balloon Ablation Catheter and Syringe (Single-Use)

Read all directions, cautions and warnings prior to use.

This instructions for use provides directions for using the ThermaChoice Uterine Balloon Therapy (UBT) Catheter.

Caution: Federal law (USA) restricts this device to sale by or on the order of a physician with appropriate training.

Caution: This product contains natural rubber latex which may cause allergic reactions.

DEVICE DESCRIPTION

The ThermaChoice UBT System is a software controlled device designed to ablate uterine tissue by thermal energy. The system is comprised of a single-use balloon catheter, a reusable controller, umbilical cable, and power cord. The ThermaChoice catheter is designed for use only with the ThermaChoice controller.

The balloon catheter is 1) connected to the controller, 2) inserted through the cervix into the uterus, 3) filled with sterile, injectable fluid (5% dextrose in water) carefully stabilizing the pressure to 160-180 mmHg pressure, and 4) activated to thermally ablate endometrial tissue by maintaining a temperature of approximately 87°C (188°F) for 8 minutes.

INDICATIONS

The ThermaChoice UBT system is a thermal ablation device intended to ablate the endometrial lining of the uterus in premenopausal women with menorrhagia (excessive uterine bleeding) due to benign causes for whom childbearing is complete.

CONTRAINDICATIONS

The device is contraindicated for use in:

- A patient who is pregnant or who wants to become pregnant in the future.
- A patient with a history of latex allergy or who has demonstrated a sensitivity to latex material.
- A patient with known or suspected endometrial carcinoma (uterine cancer) or pre-malignant change of the endometrium such as unresolved adenomatous hyperplasia.
- A patient with any anatomic or pathologic condition in which weakness of the myometrium could exist, such as history of previous classical cesarean sections or transmural myomectomy.
- A patient with active genital or urinary tract infection at the time of procedure (e.g., cervicitis, vaginitis, endometritis, salpingitis, or cystitis).
- A patient with an intrauterine device (IUD) currently in place.

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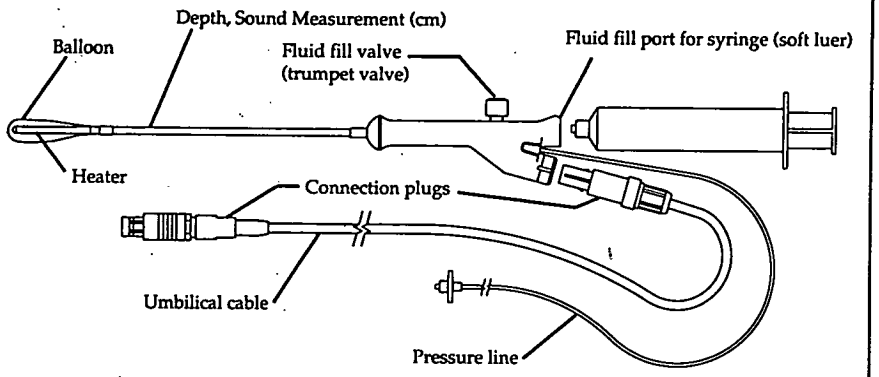
EXHIBIT

A(2)

Single-Use Balloon Catheter (GC-EAC) and Umbilical Cable (GC-EAU)



WARNINGS

Failure to follow any instructions or to heed any warnings or precautions could result in serious patient injury.

- The device is intended for use only in women who do not desire to bear children because the likelihood of pregnancy is significantly decreased following this procedure.
- Endometrial ablation using the ThermaChoice UBT System is not a sterilization procedure. Pregnancies after ablation can be dangerous for both mother and fetus.
- Endometrial ablation procedures using the ThermaChoice UBT System should be performed only by medical professionals who have experience in performing procedures within the uterine cavity such as IUD insertion or dilation and curettage (D&C) and having adequate training and familiarity with the ThermaChoice system.
- Endometrial ablation procedures do not eliminate the potential for endometrial hyperplasia, or adenocarcinoma of the endometrium and may mask the physician's ability to detect or make a diagnosis of such pathology.
- The UBT balloon catheter is for single use only — do not reuse, or resterilize.
- Do not treat patients for more than one therapy cycle in a given treatment session because of the potential for transmural injury to the uterus or injury to adjacent viscera.
- Use caution not to perforate the uterine wall when sounding the uterus or insert ing the UBT balloon catheter. **If a perforation is present, the procedure should be terminated immediately.**

PRECAUTIONS

- The UBT balloon catheter, controller, and umbilical cable are designed as a system. To ensure proper function, never use other components with the UBT system.
- A starting pressure of 160 - 180 mmHg is recommended and typically requires 6-15 cc of fluid and may require as much as 30 cc. **Titration to achieve a stable pressure (no fluctuations greater than ± 10 mmHg for at least 30 sec) prior to activating the heating element is critical to proper functioning of the device. When inserting fluid, do not exceed a pressure of 200 mmHg.** Typically, pressure levels decline slowly during the course of the procedure as the uterus relaxes. If a pressure of 160 - 180 mmHg cannot be reached with 30 cc or less of fluid, or if there is a rapid drop in pressure, remove balloon catheter and check for catheter leak and/or uterine perforation. Never add additional fluid during a therapy cycle. Rapid loss of pressure during a therapy cycle may indicate a uterine wall defect is present. Adding additional fluid to the balloon may create (or exacerbate if already present) a uterine wall defect such as a perforation.
- Those patients who have undergone endometrial ablation and are later placed on hormone replacement therapy should have a progestin included in their regimen in order to avoid the increased risk of endometrial adenocarcinoma associated with unopposed estrogen replacement therapy.
- The safety and effectiveness of the ThermaChoice UBT system has not been fully evaluated in patients:
  - with a large uterine cavity (>30 cc in volume or uterine sound >10 cm).
  - with a small uterine cavity (< 2 cc in volume or uterine sound < 6 cm).
  - with submucosal myomas, a bicornuate or septate uterus or a previous endometrial resection/ablation.
  - undergoing repeat endometrial ablation procedures.
  - who are post-menopausal.

ADVERSE EVENTS

In a study of 134 women, the most frequent events that have been reported following completion of the procedure include:

- Cramping/pelvic pain - Post-treatment cramping was reported in 91.8% of the patients which ranged from mild to severe as reported during the intra-operative period and immediate post-operative period. This cramping will typically last a few hours and rarely continues beyond the first day following ablation. The use of non-steroidal anti-inflammatory drugs (NSAIDs) prior to and following Uterine Balloon Therapy is usually sufficient to manage cramping and pelvic pain.
- Nausea and Vomiting - Nausea and vomiting were reported for 23.9% of the patients in the immediate hours following the procedure. This may be attributed to general anesthesia, and can be easily managed with medication.
- Endometritis was reported in 2.1% of patients. All patients responded to a course of oral antibiotics.
- Post-procedure symptoms such as pain, fever, nausea, vomiting, difficulty with defecation or micturition were reported. Failure of such symptoms to resolve over a reasonable period of time warrants evaluation by appropriate medical personnel.
- Hematometra was reported in 0.6% of patients treated in clinical studies conducted outside of the United States. In all patients, the hematometra was resolved with insertion of a uterine sound.
- A single perforation of the uterus was reported in a procedure conducted outside the United States.

OTHER POTENTIAL ADVERSE EFFECTS

The following adverse effects might be expected (potential), but have not yet been observed in clinical studies of the ThermaChoice UBT System:

1. **Rupture of the Uterus**
2. **Thermal Injury to Adjacent Tissue**
3. **Heated Liquid Escaping Into the Vascular Spaces and/or Cervix, Vagina, Fallopian Tubes, and Abdominal Cavity.**
4. **Electrical Burn**
5. **Allergic Reaction to Latex**
6. **Hemorrhage**
7. **Infection**
8. **Pregnancy** - Pregnancy following endometrial ablation is dangerous to both mother and fetus.
9. **Post-ablation-tubal sterilization syndrome** - This is a complication following endometrial ablation in women who have also previously undergone tubal ligation. The pathophysiology of this condition is believed to be related to the regeneration of endometrium in the cornual areas of the uterus. Blood from these glands can flow back into the proximal fallopian tubes in cases where the lower uterine segment is extensively scarred. The proximal oviduct becomes filled with blood and fluid causing symptoms similar to those of an ectopic pregnancy.

CLINICAL TRIAL

Conclusions: At twelve months of follow-up, balloon ablation was demonstrated to be at least as safe (with fewer intraoperative complications, less use of general anesthesia, and shorter procedure times), and as effective as hysteroscopic rollerball ablation in reducing menstrual bleeding to a clinically acceptable level in menorrhagic women who had completed their childbearing. Furthermore, statistically equivalent and significant reductions in patient-reported dysmenorrhea (mild, moderate, severe menstrual cramps), PMS symptoms (mild, moderate, severe common PMS symptoms), and overall impact of menses on lifestyle (scale of 1-10; 1 = none, 10 = severe) were experienced by both groups.

Purpose: The use of balloon thermal ablation for the treatment of menorrhagia for benign causes in an anatomically normal uterine cavity was compared with rollerball electrosurgical endometrial ablation with regard to safety and effectiveness. The primary effectiveness measure was a validated diary scoring system (adapted from Higham JM, O'Brien PMS, Shaw RW. Assessment of menstrual blood loss using a pictorial chart. Br J Obstet Gynaecol 1990;97:734-9). Success was defined as the reduction of excessive menstrual bleeding to normal flow or less. Secondary endpoints evaluated were overall percent decrease in diary scores and responses from a quality-of-life questionnaire. The endpoints for safety were based on the evaluation of adverse events associated with each procedure, including device-related complications, time of procedure, and type of anesthesia used.

Methods: This randomized, prospective, multicenter clinical investigation was conducted at 14 sites using investigators highly experienced with hysteroscopic rollerball endometrial ablation. All patients were ≥ 30 years old, premenopausal, and had completed childbearing. All had an anatomically normal uterine cavity ≥ 4 cm and ≤ 10 cm.

Three months of documented menorrhagia for benign causes was a requirement for inclusion and was confirmed with a diary score of at least 150 points. Endometrial biopsy and pap smear were required to rule out (pre)malignant uterine disease. No uterine thinning medications could be used for three months prior to treatment, and all patients underwent a three-minute suction curettage just prior to treatment. Selection of anesthesia regimen was left to the individual investigators. Treatment success was defined as reduction in menses to a diary score less than or equal to 75 in order to assure a return to eumenorrhea. In the original Higham study, a diary score of 100 had an 86% sensitivity and an 81% specificity for true menorrhagia for benign causes as determined by chemical analysis of the saturated pads.

Description of Patients: Two hundred seventy-five patients were randomized, 260 evaluated for safety, 255 of whom were eventually treated with either ThermaChoice Uterine Balloon Therapy (131) or rollerball ablation (124). A total of 125 UBT-treated patients and 114 rollerball-treated patients were available for Efficacy Evaluation by having completed twelve-month follow-up. Baseline demographic and gynecological variables were statistically equivalent between the two groups with regard to age (UBT 40.2 years, RB 40.9 years), race, body mass index, mean baseline diary score (UBT 552.5, RB 570.5) and other criteria.

Results:

Table 1. Effectiveness at 12 Months

	THERMACHOICE (n = 125)	ROLLERBALL (n = 114)
Study Success Rate (Diary Score ≤ 75)	80.2%*	84.3%*
Decrease to Normal Bleeding Levels or Less (Diary Score ≤ 100)	84.8%*	89.5%*
Mean Percent Decrease in Diary Scores	85.5 + 22.5**	91.7 + 12.0**
% Patients with > 90% Reduction in Diary Scores	61.6%*	68.4%*
% Patients with Diary Scores = 0	15.2%**	27.2%**
Quality-of-Life		
% Patients with Anemia Pre/Post (HCT)	29.9% / 11.6%*	29.7% / 10.6%*
Satisfaction: Very Satisfied / Satisfied	85.6% / 10.4%*	86.7% / 12.4%*
% Patients with Reduction in Dysmenorrhea	70.4%*	75.4%*
Inability to Work Outside the Home (Pre/Post-Treatment Score)	39.7%* / 4.0%*	41.9%* / 2.7%*
% Patients Reporting Severe Impact on Life Pre/Post	70.3%* / 3.2%*	78.6%* / 1.8%*

*Not statistically different (P > 0.05). **Statistically significant (P < 0.05)

Table 2. Safety at 12 Months

	THERMACHOICE (n = 134)	ROLLERBALL (n = 126)
Intra-operative Adverse Events	None (0%)	2 fluid overloads 1 cervical laceration 1 uterine perforation (3.2%)
Post-operative Adverse Events	1 post-coital bleeding 3 endometritis 1 UTI (3.7%)	1 endometritis 1 hematometra 1 PATSS[1] (2.4%)
Mean Procedure Time (minutes)	27.4**	39.6**
Cases Performed Under General Anesthesia	53.7%**	84.1%**

[1]PATSS = post-ablation-tubal-sterilization syndrome *Not statistically different (P > 0.05).
**Statistically significant (P < 0.05)

PATIENT SELECTION

Menorrhagia can be caused by a variety of underlying problems including but not limited to, endometrial cancer, myomas, polyps, anovulation, drugs, and dysfunctional uterine bleeding. Patients should always be evaluated to determine the cause of their excessive uterine bleeding before any treatment option is initiated.

Consult medical literature relative to various endometrial ablation techniques, indications, contraindications, complications, and hazards prior to the performance of any endometrial ablation procedures.

The patient selection criteria are:

- Documented diagnosis of menorrhagia for benign causes
- Completed childbearing
- Premenopausal
- Normal pap smear and endometrial biopsy
- Anatomically normal uterine cavity: standard sonography, saline infusion sonography, hysteroscopy, or hysterosalpingography within 6 months prior to performing UBT should be used to rule out submucous fibroids, large polyps, and congenital abnormalities.
- Uterine cavity depth of 6-10 cm
- Failed or contraindicated medical therapy.

PATIENT COUNSELING

As with any procedure the physician needs to discuss risks, benefits and alternatives with the patient prior to performing endometrial ablation.

The device is intended for use only in women who do not desire to bear children because the likelihood of pregnancy is significantly decreased following this procedure. Patients of childbearing capacity should be counseled that endometrial ablation is not a sterilization procedure and should be provided an appropriate birth control method. Patients with childbearing capacity should be cautioned of the potential complications which may ensue if they should become pregnant.

Vaginal discharge is typically experienced during the first few days following ablation and may last as long as a few weeks. Generally, the discharge is described as bloody during the first few days; by approximately one week, serosanguinous; then profuse and watery thereafter.

PRETREATMENT PREPARATION OF PATIENT

The lining of the uterus should be thinned prior to UBT. This can be accomplished by timing the menstrual cycle to the early proliferative phase, administering pretreatment drugs such as danocrine or GnRH agonists, or performing suction or sharp curettage immediately prior to performing the endometrial ablation. The optimum pretreatment regimes have not been determined at this time.

It is recommended that a non-steroidal anti-inflammatory drug (NSAID) be given at least one hour prior to treatment and continued post-operatively as necessary to reduce intra-operative and post-operative uterine cramping.

DIRECTIONS FOR USE

Please read all directions, cautions and warnings prior to use.

1. 0 SET-UP

1.1. The following items are required for use of the UBT System.

UBT System	Reorder # Number
1 sterile disposable UBT balloon catheter and syringe (30cc)	GC-EAC
1 umbilical cable	GC-EAU
1 controller	GC EAS
1 power cord	GC-EAP

Medical Supplies

50cc sterile injectable 5% dextrose in water (D_5W)
sterile drape for umbilical cord
tenaculum, (weighted) speculum
uterine sound, cervical dilator(s)

1.2 Open the sterile package containing the UBT balloon catheter and syringe. Disinfect umbilical cable as described at the end of this manual.

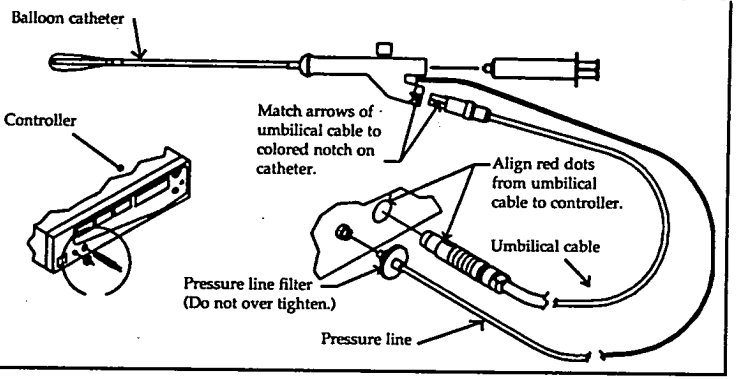
1.3 Make sure that the controller power is off before making the connection (Steps 1.4 - 1.6).

1.4 Plug the power cord into the back of the controller and into the wall outlet.

1.5 The umbilical cable includes a connector plug at each end to connect the balloon catheter to the controller. Visually inspect the cable and connector plugs to ensure there are no defects or signs of wear. Drape umbilical cable with sterile drape and attach the cable to the connector at the proximal end of the balloon catheter (match arrows of cable to colored notch on catheter). Attach the opposite end of the cable to the connection port on the front panel of controller. (Align red dots from umbilical cable to controller). (See Diagram A).

Note: When oriented correctly, the cable plugs will fit into the connectors easily and securely.

Diagram A



1.6 Connect the pressure line (pre-attached to balloon catheter) to the connection port (luer lock) on the front panel of controller. Tighten 1/4 turn only; do not overtighten (See Diagram A). Periodically clean the entrance of the controller's port, using a cotton swab with 50% ethyl alcohol.

1.7 TURN ON the controller POWER. The Message Display will read:

Message Display:
Note: N.NN = software revision level

REV. N.NN
WARMING UP

After a few seconds, the Message Display will alternate between the following messages:

Message Display:

PRIME CATHETER

and

INSERT CATHETER
FILL CATHETER

The pressure line MUST be connected to the controller BEFORE the balloon catheter is filled with fluid, or the device may not function properly.

2.0 CATHETER PRIMING

2.1 FILL the 30cc syringe with approximately 15-20cc of sterile injectable 5% dextrose in water (D_5W).

Use only sterile injectable 5% dextrose in water (D_5W). Use of other fluids may compromise system.

2.2 CONNECT syringe to the port in the proximal end of the balloon catheter. Do not overtighten syringe when connecting.

2.3 Point balloon catheter tip downward.

2.4 Press trumpet valve on top of balloon catheter handle and fill with 5-10cc of D_5W.

2.5 Press trumpet valve and evacuate fluid and air from balloon to a negative pressure of -150 to -200 mmHg (indicated by pressure display on controller).

Note: You may need to purge air from syringe several times to attain desired negative pressure. You must release trumpet valve to maintain negative pressure. Air should be completely evacuated to optimize the function of the device.

2.6 The negative pressure creates a low-profile balloon insertion (balloon is drawn tight against catheter tip). Do not go beyond -300 mmHg. Check that negative pressure is maintained for at least 10 seconds before proceeding.

If negative pressure cannot be maintained for 10 seconds, remove balloon catheter and replace.

3. PRESSURE TITRATION

3.1 Fill syringe to 30cc with D_5W, purge air, and connect to balloon catheter (do not overtighten).

3.2 Using appropriate sterile technique and cervical/vaginal preparation, dilate cervix to 5mm if necessary.

3.3 Measure depth of uterus.

3.4 Wet outside of balloon with D_5W.

3.5 After sounding uterus, and wetting balloon, **SLOWLY INSERT BALLOON CATHETER** into uterus until tip is touching the fundus. Ensure depth indicated by markings on catheter is consistent with previous sound measurement. Use a tenaculum to hold cervix if necessary.

Ensure cervical dilation to 5mm and do not use excessive force during insertion, as such force can cause the balloon to tear or the catheter to perforate the uterine wall.

3.6 Press trumpet valve on top of balloon catheter and fill balloon slowly to pressure of 160-180 mmHg using 2-30cc of D_5W (Release trumpet valve to allow pressure to stabilize). Incrementally add small volumes to achieve a stable pressure (no fluctuations greater than $\pm$ 10 mmHg) of 160-180 mmHg for a minimum of 30 seconds. The pressure of the balloon against the uterine wall often precipitates uterine relaxation, thereby temporarily decreasing pressure.

For optimal results, it is extremely important to allow pressure to stabilize to 160-180 mmHg for 30-45 seconds before pressing START (◇) button. The pressure will ultimately stabilize with careful titration.

Note: Once the heater is activated, the pressure may initially rise 10-20 mmHg; the pressure may then drop slowly for the remainder of the procedure. The ending balloon pressure may be as low as approximately 100 mmHg, and is typically between 120-150 mmHg.

Note: Activation pressure for the procedure is $\geq$ 150 mmHg. The procedure cannot start until the pressure is over 150 mmHg.

Note: It is recommended that for very small uteri, pressure titration should occur towards the lower end of the range (i.e. 160 mmHg) to minimize any potential for overpressure readings during the heating process.

Do not over pressurize balloon during titration. The controller can not display pressure > 300 mmHg.

Optimal balloon volume depends on the potential volume of the uterine cavity and is typically 6-15cc at >160 mmHg (at start) and may be as great as 30cc. If pressure level cannot be reached with 30cc of fluid, remove balloon catheter and check for uterine perforation and/or balloon catheter leak. Replace balloon catheter if necessary.

4. TREATMENT

4.1 Message Display:

READY PRESS START

When a steady pressure of 160-180 mmHg is maintained, press START (◇) button on controller to activate heater.

Do not add fluid once heater is activated, as this could result in patient injury. Hold balloon catheter immobile during procedure (with valve oriented upwards).

4.2 After the start button is pressed, the controller activates the heater to achieve treatment temperature of 87°C (188°F) within 4 minutes. (This preheat cycle may take up to 4 minutes, but is usually 15-45 seconds.)

PREHEATING TO 87°C

Note: If the treatment temperature of 87°C is not reached within 4 minutes, the controller will terminate the procedure. Remove fluid, remove catheter.

4.3 Message Display:

THERAPY CYCLE 87°C 8 MIN.

Once 87°C is reached, you will hear an audible alarm that indicates automatic activation of the 8-minute therapy cycle. Time elapsed is shown on the "TOTAL TIME" display (preheat + 8 minute therapy time).

Note: Pressure may rise slightly with initial heating. It is common to then see the pressure fall gradually during procedure.

4.4 When the treatment cycle is completed, the Message Display will alternate between the following messages:

CYCLE COMPLETE REMOVE CATHETER

and

TURN POWER OFF

4.5 The controller automatically terminates the heater at the end of the treatment (cycle) and an audible alarm will sound. Total treatment time will be displayed on controller (preheat time plus 8 minute therapy time).

5. POST-TREATMENT

5.1 **Wait approximately 30 seconds for fluid to cool** and then remove fluid by drawing back on syringe while depressing trumpet valve. Remove all fluid from balloon. Remove balloon catheter. Check that entire fluid volume is with drawn.

5.2 Disconnect catheter pressure line from controller.

5.3 Disconnect umbilical cable from catheter by holding grey shell and pulling back.

5.4 Disconnect umbilical cable from controller by holding stainless steel ribbed shell and pulling back. Do not pull on the cable itself.

5.5 Discard catheter. Retain umbilical cable and disinfect for next case.

5.6 Power must be turned off before beginning another procedure.

ORDERING INFORMATION AND RELATED PARTS AND ACCESSORIES

Reorder Number	Description
GC-EAS	UBT System Controller
GC-EAC	UBT Balloon Catheter (sterile, single-use)
GC-EAU	UBT Umbilical Cable (reusable up to 20 applications)
GC-EAP	UBT Power cord (specify country)
GC-EAM	UBT System Manual
GC-EAI	UBT Instruction card

THERMACHOICE™

Uterine Balloon Therapy

ThermaChoice UBT System Operating Manual

Gynecare inc.

technology for women's healthcare

Table of Contents

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THERMACHOICE™

Uterine Balloon Therapy

Thermal Balloon Ablation System

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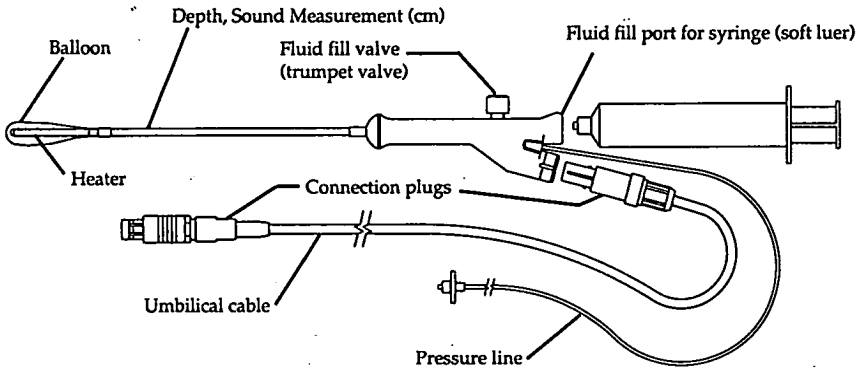
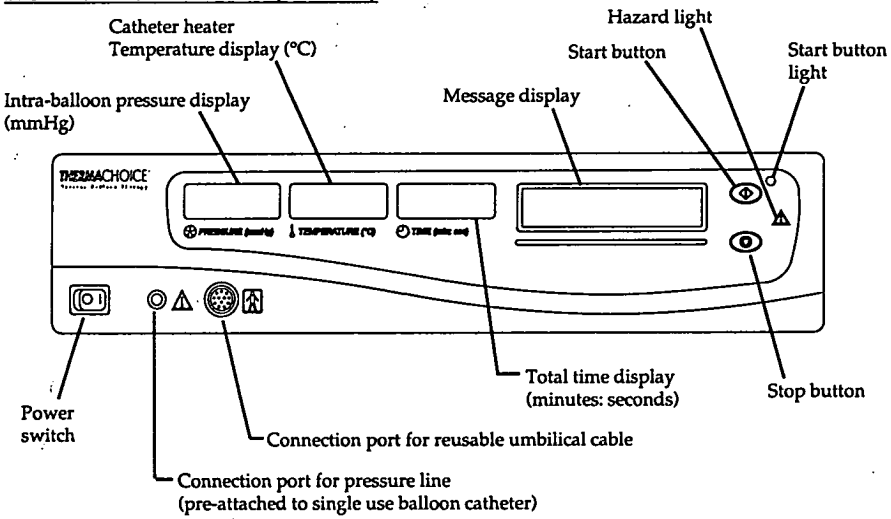
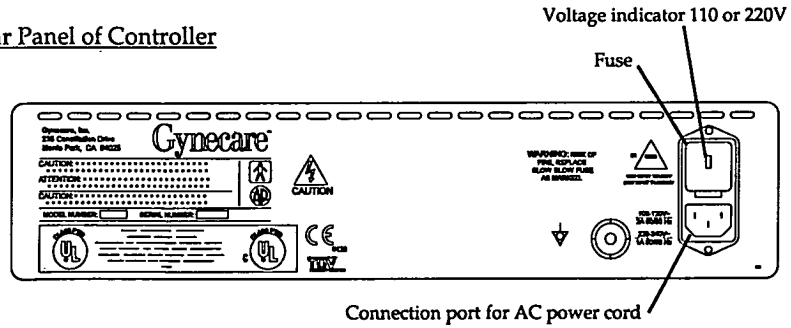
Single-Use Balloon Catheter (GC-EAC) and Umbilical Cable (GC-EAU)



Front Panel of Controller (GC-EAS)



Rear Panel of Controller



DESCRIPTION OF SYMBOLS

Front Panel of Controller

○	Off (power: disconnection from the mains)
|	On (power: connection to the mains)
◇	Start Button
▽	Stop Button
⚠	Indicates hazard condition and termination of procedure (see ERROR MESSAGES section) Red light; when on, attention, consult operator's manual.
INSERT CATHETER FILL CATHETER	Message Display- displays prompts and error messages
	Displays pressure inside balloon in mmHg
	Displays heater temperature inside balloon in °C
	Displays total running time for preheat and therapy in MINUTES: SECONDS

Rear Panel of Controller

(see SPECIFICATIONS for additional information)

	Voltage indicator (110 or 220V)
	Connection port for power cord
	Location of Fuses; Type and value rating
	Equipotentiality
	Type BF Equipment
	Cover to be removed by qualified service personnel only
	Danger: Risk of explosion if used in the presence of flammable anesthetics!
CE 0123	Notified body TUV Product Services, Munich

WARNINGS

Failure to follow any instructions or to heed any warnings or precautions could result in serious patient injury

- The device is intended for use only in women who do not desire to bear children because the likelihood of pregnancy is significantly decreased following this procedure.
- Endometrial ablation using the ThermaChoice UBT System is not a sterilization procedure. Pregnancies after ablation can be dangerous for both mother and fetus.
- Endometrial ablation procedures using the ThermaChoice UBT System should be performed only by medical professionals who have experience in performing procedures within the uterine cavity such as IUD insertion or dilation and curettage (D&C) and having adequate training and familiarity with the ThermaChoice system.
- Endometrial ablation procedures do not eliminate the potential for endometrial hyperplasia, or adenocarcinoma of the endometrium and may mask the physician's ability to detect or make a diagnosis of such pathology.
- The UBT balloon catheter is for single use only — do not reuse, or resterilize.
- Do not treat patients for more than one therapy cycle in a given treatment session because of the potential for transmural injury to the uterus or injury to adjacent viscera.
- Use caution not to perforate the uterine wall when sounding the uterus or inserting the UBT balloon catheter. **If a perforation is present, the procedure should be terminated immediately.**

PRECAUTIONS

- The UBT balloon catheter, controller, and umbilical cable are designed as a system. To ensure proper function, never use other components with the UBT system.
- A starting pressure of 160 - 180 mmHg is recommended and typically requires 6-15 cc of fluid and may require as much as 30 cc. **Titration to achieve a stable pressure (no fluctuations greater than ± 10 mmHg for at least 30 sec) prior to activating the heating element is critical to proper functioning of the device. When inserting fluid, do not exceed a pressure of 200 mmHg.** Typically, pressure levels decline slowly during the course of the procedure as the uterus relaxes. If a pressure of 160 - 180 mmHg cannot be reached with 30 cc or less of fluid, or if there is a rapid drop in pressure, remove balloon catheter and check for catheter leak and/or uterine perforation. Never add additional fluid during a therapy cycle. Rapid loss of pressure during a therapy cycle may indicate a uterine wall defect is present. Adding additional fluid to the balloon may create (or exacerbate if already present) a uterine wall defect such as a perforation.
- Those patients who have undergone endometrial ablation and are later placed on hormone replacement therapy should have a progestin included in their regimen in order to avoid the increased risk of endometrial adenocarcinoma associated with unopposed estrogen replacement therapy.
- The safety and effectiveness of the ThermaChoice UBT system has not been fully evaluated in patients:
  - with a large uterine cavity (>30 cc in volume or uterine sound >10 cm).
  - with a small uterine cavity (< 2 cc in volume or uterine sound < 6 cm).
  - with submucosal myomas, a bicornuate or septate uterus or a previous endometrial resection/ablation.
  - undergoing repeat endometrial ablation procedures.
  - who are post-menopausal.

ADVERSE EVENTS

In a study of 134 women, the most frequent events that have been reported following completion of the procedure include:

- Cramping/pelvic pain - Post-treatment cramping was reported in 91.8% of the patients which ranged from mild to severe as reported during the intra-operative period and immediate post-operative period. This cramping will typically last a few hours and rarely continues beyond the first day following ablation. The use of non-steroidal anti-inflammatory drugs (NSAIDs) prior to and following Uterine Balloon Therapy is usually sufficient to manage cramping and pelvic pain.
- Nausea and Vomiting - Nausea and vomiting were reported for 23.9% of the patients in the immediate hours following the procedure. This may be attributed to general anesthesia, and can be easily managed with medication.
- Endometritis was reported in 2.1% of patients. All patients responded to a course of oral antibiotics.
- Post-procedure symptoms such as pain, fever, nausea, vomiting, difficulty with defecation or micturition were reported. Failure of such symptoms to resolve over a reasonable period of time warrants evaluation by appropriate medical personnel.
- Hematometra was reported in 0.6% of patients treated in clinical studies conducted outside of the United States. In all patients, the hematometra was resolved with insertion of a uterine sound.
- A single perforation of the uterus was reported in a procedure conducted outside the United States.

OTHER POTENTIAL ADVERSE EFFECTS

The following adverse effects might be expected (potential), but have not yet been observed in clinical studies of the ThermaChoice UBT System:

1. **Rupture of the Uterus**
2. **Thermal Injury to Adjacent Tissue**
3. **Heated Liquid Escaping Into the Vascular Spaces and/or Cervix, Vagina, Fallopian Tubes, and Abdominal Cavity.**
4. **Electrical Burn**
5. **Allergic Reaction to Latex**
6. **Hemorrhage**
7. **Infection**
8. **Pregnancy** - Pregnancy following endometrial ablation is dangerous to both mother and fetus.

9. **Post-ablation-tubal sterilization syndrome** - This is a complication following endometrial ablation in women who have also previously undergone tubal ligation. The pathophysiology of this condition is believed to be related to the regeneration of endometrium in the cornual areas of the uterus. Blood from these glands can flow back into the proximal fallopian tubes in cases where the lower uterine segment is extensively scarred. The proximal oviduct becomes filled with blood and fluid causing symptoms similar to those of an ectopic pregnancy.

CLINICAL TRIAL

Conclusions: At twelve months of follow-up, balloon ablation was demonstrated to be at least as safe (with fewer intraoperative complications, less use of general anesthesia, and shorter procedure times), and as effective as hysteroscopic rollerball ablation in reducing menstrual bleeding to a clinically acceptable level in menorrhagic women who had completed their childbearing. Furthermore, statistically equivalent and significant reductions in patient-reported dysmenorrhea (mild, moderate, severe menstrual cramps), PMS symptoms (mild, moderate, severe common PMS symptoms), and overall impact of menses on lifestyle (scale of 1-10; 1 = none, 10 = severe) were experienced by both groups.

Purpose: The use of balloon thermal ablation for the treatment of menorrhagia for benign causes in an anatomically normal uterine cavity was compared with rollerball electrosurgical endometrial ablation with regard to safety and effectiveness. The primary effectiveness measure was a validated diary scoring system (adapted from Higham JM, O'Brien PMS, Shaw RW. Assessment of menstrual blood loss using a pictorial chart. Br J Obstet Gynaecol 1990;97:734-9). Success was defined as the reduction of excessive menstrual bleeding to normal flow or less. Secondary endpoints evaluated were overall percent decrease in diary scores and responses from a quality-of-life questionnaire. The endpoints for safety were based on the evaluation of adverse events associated with each procedure, including device-related complications, time of procedure, and type of anesthesia used.

Methods: This randomized, prospective, multicenter clinical investigation was conducted at 14 sites using investigators highly experienced with hysteroscopic rollerball endometrial ablation. All patients were ≥ 30 years old, premenopausal, and had completed childbearing. All had an anatomically normal uterine cavity > 4 cm and < 10 cm.

Three months of documented menorrhagia for benign causes was a requirement for inclusion and was confirmed with a diary score of at least 150 points. Endometrial biopsy and pap smear were required to rule out (pre)malignant uterine disease. No uterine thinning medications could be used for three months prior to treatment, and all patients underwent a three-minute suction curettage just prior to treatment. Selection of anesthesia regimen was left to the individual investigators. Treatment success was defined as reduction in menses to a diary score less than or equal to 75 in order to assure a return to eumenorrhea. In the original Higham study, a diary score of 100 had an 86% sensitivity and an 81% specificity for true menorrhagia for benign causes as determined by chemical analysis of the saturated pads.

Description of Patients: Two hundred seventy-five patients were randomized, 260 evaluated for safety, 255 of whom were eventually treated with either ThermaChoice Uterine Balloon Therapy (131) or rollerball ablation (124). A total of 125 UBT-treated patients and 114 rollerball-treated patients were available for Efficacy Evaluation by having completed twelve-month follow-up. Baseline demographic and gynecological variables were statistically equivalent between the two groups with regard to age (UBT 40.2 years, RB 40.9 years), race, body mass index, mean baseline diary score (UBT 552.5, RB 570.5) and other criteria.

Results:

Table 1. Effectiveness at 12 Months

	THERMACHOICE (n = 125)	ROLLERBALL (n = 114)
Study Success Rate (Diary Score ≤ 75)	80.2%*	84.3%*
Decrease to Normal Bleeding Levels or Less (Diary Score ≤ 100)	84.8%*	89.5%*
Mean Percent Decrease in Diary Scores	85.5 + 22.5**	91.7 + 12.0**
% Patients with > 90% Reduction in Diary Scores	61.6%*	68.4%*
% Patients with Diary Scores = 0	15.2%**	27.2%**
Quality-of-Life		
% Patients with Anemia Pre/Post (HCT)	29.9% / 11.6%*	29.7% / 10.6%*
Satisfaction: Very Satisfied / Satisfied	85.6% / 10.4%*	86.7% / 12.4%*
% Patients with Reduction in Dysmenorrhea	70.4%*	75.4%*
Inability to Work Outside the Home (Pre/Post-Treatment Score)	39.7%* / 4.0%*	41.9%* / 2.7%*
% Patients Reporting Severe Impact on Life Pre/Post	70.3%* / 3.2%*	78.6%* / 1.8%*

*Not statistically different (P > 0.05). **Statistically significant (P < 0.05)

Table 2. Safety at 12 Months

	THERMACHOICE (n = 134)	ROLLERBALL (n = 126)
Intra-operative Adverse Events	None (0%)	2 fluid overloads 1 cervical laceration 1 uterine perforation (3.2%)
Post-operative Adverse Events	1 post-coital bleeding 3 endometritis 1 UTI (3.7%)	1 endometritis 1 hematometra 1 PATSS[1] (2.4%)
Mean Procedure Time (minutes)	27.4**	39.6**
Cases Performed Under General Anesthesia	53.7%**	84.1%**

[1]PATSS = post-ablation-tubal-sterilization syndrome *Not statistically different (P > 0.05).
**Statistically significant (P < 0.05)

PATIENT SELECTION

Menorrhagia can be caused by a variety of underlying problems including but not limited to, endometrial cancer, myomas, polyps, anovulation, drugs, and dysfunctional uterine bleeding. Patients should always be evaluated to determine the cause of their excessive uterine bleeding before any treatment option is initiated.

Consult medical literature relative to various endometrial ablation techniques, indications, contraindications, complications, and hazards prior to the performance of any endometrial ablation procedures.

The patient selection criteria are:

- Documented diagnosis of menorrhagia for benign causes
- Completed childbearing
- Premenopausal

- Normal pap smear and endometrial biopsy
- Anatomically normal uterine cavity: standard sonography, saline infusion sonography, hysteroscopy, or hysterosalpingography within 6 months prior to performing UBT should be used to rule out submucous fibroids, large polyps, and congenital abnormalities.
- Uterine cavity depth of 6-10 cm
- Failed or contraindicated medical therapy.

PATIENT COUNSELING

As with any procedure the physician needs to discuss risks, benefits and alternatives with the patient prior to performing endometrial ablation.

The device is intended for use only in women who do not desire to bear children because the likelihood of pregnancy is significantly decreased following this procedure. Patients of childbearing capacity should be counseled that endometrial ablation is not a sterilization procedure and should be provided an appropriate birth control method. Patients with childbearing capacity should be cautioned of the potential complications which may ensue if they should become pregnant.

Vaginal discharge is typically experienced during the first few days following ablation and may last as long as a few weeks. Generally, the discharge is described as bloody during the first few days; by approximately one week, serosanguinous; then profuse and watery thereafter.

PRETREATMENT PREPARATION OF PATIENT

The lining of the uterus should be thinned prior to UBT. This can be accomplished by timing the menstrual cycle to the early proliferative phase, administering pretreatment drugs such as danocrine or GnRH agonists, or performing suction or sharp curettage immediately prior to performing the endometrial ablation. The optimum pretreatment regimes have not been determined at this time.

It is recommended that a non-steroidal anti-inflammatory drug (NSAID) be given at least one hour prior to treatment and continued post-operatively as necessary to reduce intra-operative and post-operative uterine cramping.

DIRECTIONS FOR USE

Please read all directions, cautions and warnings prior to use.

1. 0 SET-UP

1.1. The following items are required for use of the UBT System.

UBT System	Reorder # Number
1 sterile disposable UBT balloon catheter and syringe (30cc)	GC-EAC
1 umbilical cable	GC-EAU
1 controller	GC EAS
1 power cord	GC-EAP

Medical Supplies

50cc sterile injectable 5% dextrose in water (D_5W)
sterile drape for umbilical cord
tenaculum, (weighted) speculum
uterine sound, cervical dilator(s)

1.2 Open the sterile package containing the UBT balloon catheter and syringe. Disinfect umbilical cable as described at the end of this manual.

1.3 Make sure that the controller power is off before making the connection (Steps 1.4 - 1.6).

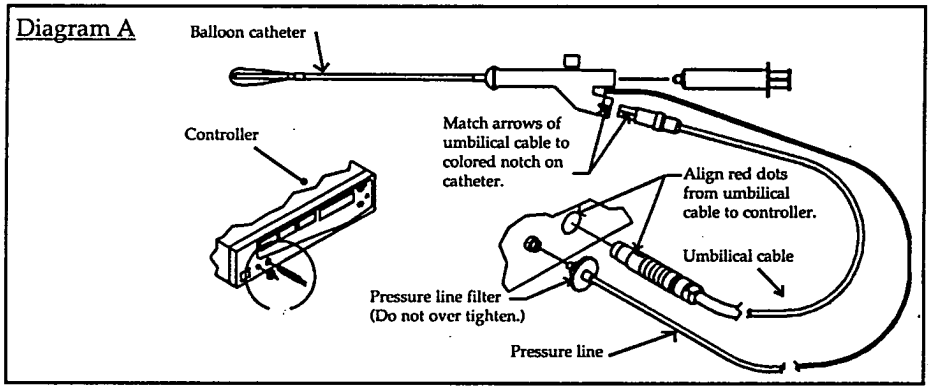
1.4 Plug the power cord into the back of the controller and into the wall outlet.

1.5 The umbilical cable includes a connector plug at each end to connect the balloon catheter to the controller. Visually inspect the cable and connector plugs to ensure there are no defects or signs of wear. Drape umbilical cable with sterile drape and attach cable to the connector at the proximal end of the balloon catheter (match arrows of cable to colored notch on catheter). Attach the opposite end of the cable to the connection port on the front panel of controller. (Align red dots from umbilical cable to controller). (See Diagram A).

Note: When oriented correctly, the cable plugs will fit into the connectors easily and securely.

1.6 Connect the pressure line (pre-attached to balloon catheter) to the connection port (luer lock) on the front panel of controller. Tighten 1/4 turn only; do not over-tighten (See Diagram A). Periodically clean the entrance of the controller's port, using a cotton swab with 50% ethyl alcohol.

Diagram A



1.7 TURN ON the controller POWER. The Message Display will read:

Message Display:
Note: N.NN = software revision level

REV. N.NN WARMING UP

After a few seconds, the Message Display will alternate between the following messages:

Message Display:

PRIME CATHETER

and

INSERT CATHETER FILL CATHETER

The pressure line MUST be connected to the controller BEFORE the balloon catheter is filled with fluid, or the device may not function properly.

2.0 CATHETER PRIMING

2.1 FILL the 30cc syringe with approximately 15-20cc of sterile injectable 5% dextrose in water (D_5W).

Use only sterile injectable 5% dextrose in water (D_5W). Use of other fluids may compromise system.

2.2 CONNECT syringe to the port in the proximal end of the balloon catheter. Do not overtighten syringe when connecting.

2.3 Point balloon catheter tip downward.

2.4 Press trumpet valve on top of balloon catheter handle and fill with 5-10cc of D_5W.

2.5 Press trumpet valve and evacuate fluid and air from balloon to a negative pressure of -150 to -200 mmHg (indicated by pressure display on controller).

Note: You may need to purge air from syringe several times to attain desired negative pressure. You must release trumpet valve to maintain negative pressure. Air should be completely evacuated to optimize the function of the device.

2.6 The negative pressure creates a low-profile balloon insertion (balloon is drawn tight against catheter tip). Do not go beyond -300 mmHg. Check that negative pressure is maintained for at least 10 seconds before proceeding.

If negative pressure cannot be maintained for 10 seconds, remove balloon catheter and replace.

3. PRESSURE TITRATION

3.1 Fill syringe to 30cc with D_5W, purge air, and connect to balloon catheter (do not overtighten).

3.2 Using appropriate sterile technique and cervical/vaginal preparation, dilate cervix to 5mm if necessary.

3.3 Measure depth of uterus.

3.4 Wet outside of balloon with D_5W.

3.5 After sounding uterus, and wetting the balloon, **SLOWLY INSERT BALLOON CATHETER** into uterus until tip is touching the fundus. Ensure depth indicated by markings on catheter is consistent with previous sound measurement. Use a tenaculum to hold cervix if necessary.

Ensure cervical dilation to 5mm and do not use excessive force during insertion, as such force can cause the balloon to tear or the catheter to perforate the uterine wall.

3.6 Press trumpet valve on top of balloon catheter and fill balloon slowly to pressure of 160-180 mmHg using 2-30cc of D_5W (Release trumpet valve to allow pressure to stabilize). Incrementally add small volumes to achieve a stable pressure (no fluctuations greater than $\pm$ 10 mmHg) of 160-180 mmHg for a minimum of 30 seconds. The pressure of the balloon against the uterine wall often precipitates uterine relaxation, thereby temporarily decreasing pressure.

For optimal results, it is extremely important to allow pressure to stabilize to 160-180 mmHg for 30-45 seconds before pressing START (◇) button. The pressure will ultimately stabilize with careful titration.

Note: Once the heater is activated, the pressure may initially rise 10-20 mmHg; the pressure may then drop slowly for the remainder of the procedure. The ending balloon pressure may be as low as approximately 100 mmHg, and is typically between 120-150 mmHg.

Note: Activation pressure for the procedure is $\geq$ 150 mmHg. The procedure cannot start until the pressure is over 150 mmHg.

Note: It is recommended that for very small uteri, pressure titration should occur towards the lower end of the range (i.e. 160 mmHg) to minimize any potential for overpressure readings during the heating process.

Do not over pressurize balloon during titration. The controller can not display pressure > 300 mmHg.

Optimal balloon volume depends on the potential volume of the uterine cavity and is typically 6-15cc at >160 mmHg (at start) and may be as great as 30cc. If pressure level cannot be reached with 30cc of fluid, remove balloon catheter and check for uterine perforation and/or balloon catheter leak. Replace balloon catheter if necessary.

4. TREATMENT

4.1 Message Display:

READY PRESS START

When a steady pressure of 160-180 mmHg is maintained, press START (◇) button on controller to activate heater.

Do not add fluid once heater is activated, as this could result in patient injury. Hold balloon catheter immobile during procedure (with valve oriented upwards).

4.2 After the start button is pressed, the controller activates the heater to achieve treatment temperature of 87°C (188°F) within 4 minutes. (This preheat cycle may take up to 4 minutes, but is usually 15-45 seconds.)

PREHEATING TO 87°C

Note: If the treatment temperature of 87°C is not reached within 4 minutes, the controller will terminate the procedure. Remove fluid, remove catheter.

4.3 Message Display:

THERAPY CYCLE 87°C 8 MIN.

Once 87°C is reached, you will hear an audible alarm that indicates automatic activation of the 8 minute therapy cycle. Time elapsed is shown on the "TOTAL TIME" display (preheat + 8 minute therapy time).

Note: Pressure may rise slightly with initial heating. It is common to then see the pressure fall gradually during procedure.

4.4 When the treatment cycle is completed, the Message Display will alternate between the following messages:

CYCLE COMPLETE REMOVE CATHETER

and

TURN POWER OFF

4.5 The controller automatically terminates the heater at the end of the treatment (cycle) and an audible alarm will sound. Total treatment time will be displayed on controller (preheat time plus 8 minute therapy time).

5. POST-TREATMENT

5.1 **Wait approximately 30 seconds for fluid to cool** and then remove fluid by drawing back on syringe while depressing trumpet valve. Remove all fluid from balloon. Remove balloon catheter. Check that entire fluid volume is with drawn.

5.2 Disconnect catheter pressure line from controller.

5.3 Disconnect umbilical cable from catheter by holding grey shell and pulling back.

5.4 Disconnect umbilical cable from controller by holding stainless steel ribbed shell and pulling back. Do not pull on the cable itself.

5.5 Discard catheter. Retain umbilical cable and disinfect for next case.

5.6 Power must be turned off before beginning another procedure.

OPERATING PARAMETERS / ALARM AND DISPLAY MESSAGES

The controller is designed to monitor time, temperature and pressure within parameters preset at the factory.

- ALERT. If the temperature and/or pressure increases or falls beyond a level pre-set at the factory, the controller will sound a short audible alert.
- HAZARD ALARM/TERMINATION OF PROCEDURE (HEATER SHUT OFF LIMITS). If the temperature and/or pressure increases or falls outside the operating parameters, the controller will sound an alarm, terminate the procedure and display an error message. Additionally, if the controller detects a system failure, the procedure will be terminated. If the procedure is terminated, the Message Display will display a message indicating the cause.

The following chart explains operating parameters for temperature, time, and pressure.

	Standard	Range	Alarm/Heater Shut Off Limits	
Temperature	87°C	75-90°C	Over Under	≥95°C for 2 sec or be- ≤75°C for 15 sec*
Pressure	Titrate to 160-180 mmHg before starting procedure; Activation Pressure (Minimum starting pressure) ≥ 150 mmHg	45-210 mmHg	Over Under	≥210 mmHg ≤45 mmHg
Time	8 minute therapy cycle after reaching 87°C (preheat phase)		Over	>4 minute pre-heat

*or failure to achieve temperature of 87°C within 4 minute preheat phase.

When parameters extend outside the normal operating range, the controller sounds an audible alert (intended only as warning signals to the clinician). These values are listed below and reside between normal operating and termination parameters (see previous chart):

		Alert (Warning)
Temperature	Over	> 90°C & < 95°C for 2 seconds
	Under	< 83°C for 2 seconds
Pressure	Over	> 200 mmHg & < 210 mmHg for 2 seconds
	Under	> 45 mmHg & < 70 mmHg for 2 seconds

ERROR MESSAGES

Under electrostatic discharge to the controller or abnormal line voltage conditions, i.e. surge and fast transients, the system may terminate the procedure. The message display may be blank or may indicate an error code. If any of these occur turn off the power to the controller and restart the procedure.

In addition to the operating messages listed in the "Directions," the Message Display also provides messages which indicate conditions under which the controller either will not begin treatment or will terminate treatment after the heating cycle has been initiated.

Prior to pressing START (◇) — the following error messages indicate conditions under which the controller will not begin therapy cycle until corrected:

MESSAGE DISPLAY	REASON	ACTION
CONNECT CATHETER	Balloon catheter and/or umbilical cable is not connected.	Connect balloon catheter. Ensure connections are secure.
CATHETER ERROR REPLACE CATHETER	Balloon catheter and/or umbilical cable is not functioning properly.	Replace balloon catheter and/or umbilical cable.
SYSTEM ERROR TURN POWER OFF	System is not functioning properly.	Return controller for repair.

After pressing START (◇) -- the following error messages indicate conditions under which the controller will terminate the procedure and disable the heating element after the therapy cycle has begun:

MESSAGE DISPLAY	REASON	ACTION
CATHETER ERROR END PROCEDURE	Balloon catheter is not functioning properly.	Remove fluid. Remove balloon catheter.
SYSTEM ERROR or HEATER ERROR and END PROCEDURE	System is not functioning properly.	Remove fluid. Remove balloon catheter. Return controller for repair.
PREHEAT ERROR or OVERHEAT ERROR or PRESSURE ERROR and END PROCEDURE	Treatment temperature and/or pressure is outside standard operating parameters.	Remove fluid. Remove balloon catheter.

WARRANTY

Gynecare, Inc., warrants the original purchase of the Gynecare UBT System Controller shall be free of defects in material and workmanship when used as intended under normal surgical conditions and in conformance with its directions for use and maintenance instructions. The obligation of Gynecare, Inc., under this warranty shall be limited to the repair or replacement, each at no charge, at the option of Gynecare, Inc., within one year from the date of purchase, if examination shall disclose to the satisfaction of Gynecare, Inc., that the controller does not meet this warranty.

THIS WARRANTY IS MADE IN LIEU OF ALL OTHER WARRANTIES EXPRESSED OR IMPLIED INCLUDING THE WARRANTIES OF MERCHANTABILITY AND FITNESS FOR USE AND ALL OTHER OBLIGATIONS AND LIABILITIES ON THE PART OF GYNECARE. GYNECARE, INC., NEITHER ASSUMES NOR AUTHORIZES ANY OTHER PERSON TO ASSUME FOR IT, ANY OTHER LIABILITY IN CONNECTION WITH THE SALE OF A GYNECARE CONTROLLER. THIS WARRANTY SHALL NOT APPLY TO A GYNECARE CONTROLLER OR ANY PART THEREOF WHICH HAS BEEN SUBJECT TO ACCIDENT, NEGLIGENCE, ALTERATION, ABUSE, OR MISUSE, NOR TO ANY GYNECARE, INC., CONTROLLER THAT HAS BEEN REPAIRED OR ALTERED BY ANYONE OTHER THAN AN AUTHORIZED GYNECARE SERVICE PERSON, MAKES NO WARRANTY WHATSOEVER WITH REGARD TO ACCESSORIES OR PARTS USED IN CONJUNCTION WITH THE GYNECARE, INC. CONTROLLER AND NOT SUPPLIED AND MANUFACTURED BY GYNECARE, INC. THE TERM "ORIGINAL PURCHASER", AS USED IN THE WARRANTY, SHALL BE DEEMED TO MEAN THAT PERSON OR ORGANIZATION AND ITS EMPLOYEES, IF APPLICABLE, TO WHOM THE GYNECARE CONTROLLER WAS SOLD BY GYNECARE, INC. THIS WARRANTY MAY NOT BE ASSIGNED OR TRANSFERRED IN ANY MANNER.

Should any Gynecare, Inc. controller become inoperable after the one year period of this Warranty or should damage occur which is not covered under the terms of this Warranty, Gynecare, Inc. will, upon request, be willing to repair the controller, if possible, for an appropriate handling and repair charge.

SERVICE

Should the UBT System Controller become inoperable contact Gynecare's Customer Service Department for instructions and a return material authorization number. Clean and repackage the controller appropriately and return it for repair, servicing and/or modification to the authorized locations listed below. If the controller is not under warranty, an appropriate handling and repair charge will be established after receipt and examination of the controller.

For service, technical support or reorder information, contact in the U.S.:
Gynecare, Inc.
Ethicon, Inc.
A Johnson & Johnson Company
235 Constitution Drive
Menlo Park, CA 94025
Phone: (650) 614-2500
Toll Free: (800) 336-4963
Fax: (650) 462-6742

Note: Any device related incidence or problems which are felt to represent a safety issue, should be reported to Gynecare's Customer Service Department or Authorized European Representative.

AUTHORIZED EUROPEAN REPRESENTATIVE

ETHICON France
une divson ETHNOR S.A.
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Roma
Italia
Tel: 06/911 944 32

ORDERING INFORMATION AND RELATED PARTS AND ACCESSORIES

Reorder Number	Description
GC-EAS	UBT System Controller
GC-EAC	UBT Balloon Catheter (sterile, single-use)
GC-EAU	UBT Umbilical Cable (reusable up to 20 applications)
GC-EAP	UBT Power cord (specify country)
GC-EAM	UBT System Manual
GC-EAI	UBT Instruction card

SPECIFICATIONS (CONTROLLER AND UMBILICAL CABLE)

Power Requirements	110 to 120 V; 50/60 Hz; 2A; 3-wire grounded system or 220-240V; 50/60 Hz; 1A; 3-wire grounded system
Mains Fuses	110-120VAC, 5x20mm T3A 250V Slow blow 220-240VAC, 5x20mm T1.6A 250V Slow blow
Heater Fuses	T5A 250V
Dimensions	Height 10.2cm (4in.), width 41.2cm (16.25in.), depth 37.0cm (14.56 in.)
Weight	6.9 kg (15.3 lb) (controller only)
Case	Aluminum and impact-resistant plastic
Umbilical Cable	Length 152 cm (60 in.)

MAINTENANCE

1.0 CALIBRATION:

Every time the UBT system is powered up, the controller zeros out the offsets that may be present on the measurement circuitry, and therefore automatically provides a single point calibration. In addition, the pressure sensor utilized in the controller is internally calibrated and temperaure compensated and is accurate and stable over the operating range. These sensors are of differential type, and therefore measure the balloon pressure relative to the outside atmosphere. In addition to the internal means of calibration, it is possible to ensure the proper operation of the system against other calibrated devices. This procedure is recommended to be performed on an annual basis. The procedure also needs to be carried out if it is believed that the system is behaving unexpectedly.

Note: There are no calibration adjustments on the controller. If the unit does not meet the calibration requirements, it needs to be sent back to the manufacturer.

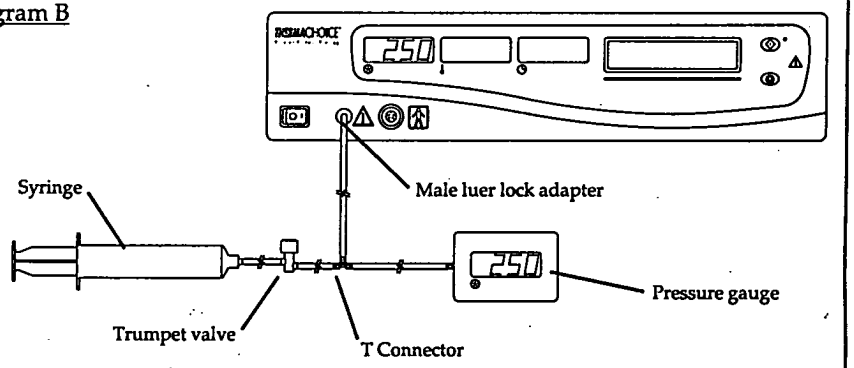
1.1. PRESSURE CALIBRATION

1.1.1. Equipment List

The following equipment list or equivalent is needed to perform the procedure:

1. Pressure meter: DigiMano model DPM 2000PS. NETECH Corporation, 60 Bethpage Drive, Hickville, NY 11801, Telephone: (800) 547-6557/ (Any calibrated, NBS traceable pressure gauge with a range of at least ± 6 psi can be used).
2. Syringe: PN 309662, Becton-Dickinson. State Surgical Supply, 3380 Vincent Rd. # C, Pleasant Hill, CA 94523, Telephone: (510) 284-1060.
3. Trumpet valve: PN S5402601, Braun Medical, Inc., 824 Twelfth Ave, PO Box 4027, Bethlehem, PA 18018-0027, Telephone: (610) 266-0500.
4. T connector: PN T20-1, Value Plastics, Inc., 3350 Eastbrook Dr., Fort Collins, CO 80525, Telephone: (970) 223-0953.
5. Tubing: 0.093 ID, 0.156 OD, Norton Performance Plastics Corp, PO Box3660, Akron OH 44309-3660, Telephone: (800) 798-1539.
6. Male luer lock adapter: PN B0850402, Braun Medical, Inc., 824 Twelfth Ave., PO Box 4027, Bethlehem, PA 18018-0027, Telephone: (610) 266-0500.

Diagram B



1.1.2. Procedure

1. With no attachments to the luer lock, apply power to the controller. The pressure display should read 0±10 mmHg.
2. Assemble the digital pressure gauge, the tubing, the T connector, the trumpet valve, the male luer lock adapter, and the syringe as shown in Diagram B, and connect to the connection port (luer lock) of the controller.
3. While depressing the trumpet valve, apply vacuum to the system using the syringe until the gauge reads approximately -250 mmHg.
4. Release the trumpet valve. The controller pressure reading should be within ± 10 mmHg of the gauge reading.
5. While depressing the trumpet valve, apply pressure to the system until the reading on the digital display meter indicates a pressure of approximately 250 mmHg.

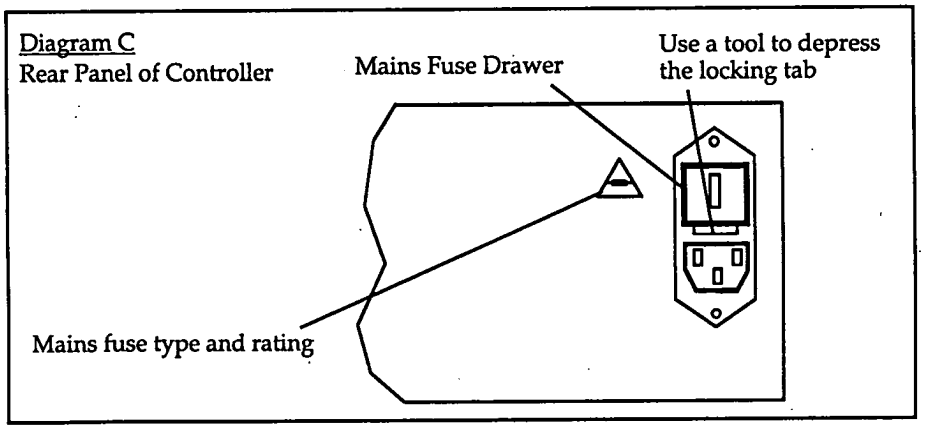
6. Release the trumpet valve. The controller pressure reading should be within ± 10 mmHg of the gauge reading.

1.2. TEMPERATURE CALIBRATION

1. Obtain a calibrated digital or glass thermometer.
2. Place this thermometer in close proximity to a new UBT catheter tip and allow them to come to thermal equilibrium with the ambient.
3. Connect the catheter to the controller using the umbilical cable as described earlier in the manual.
4. Power up the controller.
5. Note the thermometer reading and compare to that of the controller. The readings should be within ± 5 degrees Celsius.
6. Insert the balloon end of the catheter along with the thermometer in 80-90 degree Celsius water.
7. Allow a few minutes for the catheter and the thermometer to come to thermal equilibrium.
8. Compare the two temperature readings. They should be within ± 5 degrees Celsius.

2.0 FUSE REPLACEMENT:

Fuse: In the event of a main fuse failure, turn off the power and unplug the rear of the controller to allow fuse access. Using a tool such as a screwdriver, remove the fuse drawer by depressing the locking tab. See Diagram C below:



Replace both fuses with the same type and rating as specified on the rear of the controller. Reinsert the fuse drawer until the locking tab snaps into place. Reconnect the power cord and restore power to the controller. If a fuse fails again, disconnect all power to the controller and return it to Gynecare.

All other service must be performed by appropriately qualified technical personnel. Field repair, other than the controller's external fuse replacement voids all warranties and may not be performed without express authorization from Gynecare.

3.0 CLEANING: CONTROLLER SYSTEM

It is good practice to routinely clean the exterior surface of the device.

1. Disconnect all umbilical cables and unplug the power cord from the wall outlet before cleaning.
2. Use a cloth dampened with 50% water and 50% isopropyl alcohol, or a mild, nonabrasive detergent (such as commercially available dish cleaning liquid) mixed with water.
3. Periodically clean the entrance of the controller's port (luer lock) using a cotton swab with 50% isopropyl alcohol.

Do not autoclave, ETO sterilize, or immerse the controller or umbilical cable in a liquid. Do not allow liquids to enter the controller during cleaning.

4.0 DISINFECTION: UMBILICAL CABLE

The UBT Umbilical Cable is packaged non-sterile. After each use, the cable should be disinfected. To disinfect, wipe down the cable with a damp cloth using a solution of 50% water and 50% isopropyl alcohol. Use only 50% water and 50% isopropyl alcohol. Ensure that the cable and connectors are completely dry. Inspect the cable and the connector plugs before each use for signs of wear and replace if necessary. The umbilical has been validated for 20 cycles. Following 20 uses, discard the cable, and replace.

5.0 POWER CORD

Users in North America operating from a nominal 120 Vac system must select a Type SJT, SJTO, SJO, or SJE, Hospital Grade cord set. The power supply cord must be marked "Grounding Reliability can only be achieved when the equipment is connected to an equivalent receptacle marked "Hospital Grade" or "Hospital Only"".

US005105808A

United States Patent [19]

Neuwirth et al.

[11] Patent Number: 5,105,808

[45] Date of Patent: Apr. 21, 1992

[54] INTRAUTERINE CAUTERIZING METHOD

[75] Inventors: Robert S. Neuwirth, Englewood, N.J.; Lee R. Bolduc, Raleigh, N.C.

[73] Assignee: Gynelab Products, Raleigh, N.C.

[21] Appl. No.: 565,154

[22] Filed: Aug. 9, 1990

Related U.S. Application Data

[62] Division of Ser. No. 242,730, Sep. 9, 1988, Pat. No. 4,949,718.

[51] Int. Cl.[5] A61F 7/12

[52] U.S. Cl. 128/401; 606/27

[58] Field of Search 128/6, 399–402; 604/99; 606/27, 28

[56] References Cited

U.S. PATENT DOCUMENTS

1,786,373	12/1930	Walker .	
1,951,904	3/1934	Garshelis	123/254
2,078,686	4/1937	Rowe	128/255
2,190,383	2/1940	Newman	128/401
3,924,628	12/1975	Droegemueller et al.	606/21
4,137,922	2/1979	Leininger et al.	128/344
4,160,455	7/1979	Law	128/400
4,574,752	7/1988	Ginsburg et al.	606/27
4,676,258	6/1987	Inokuchi et al.	128/804
4,686,965	8/1987	Bennet et al.	128/4
4,799,479	1/1989	Spears	606/28

FOREIGN PATENT DOCUMENTS

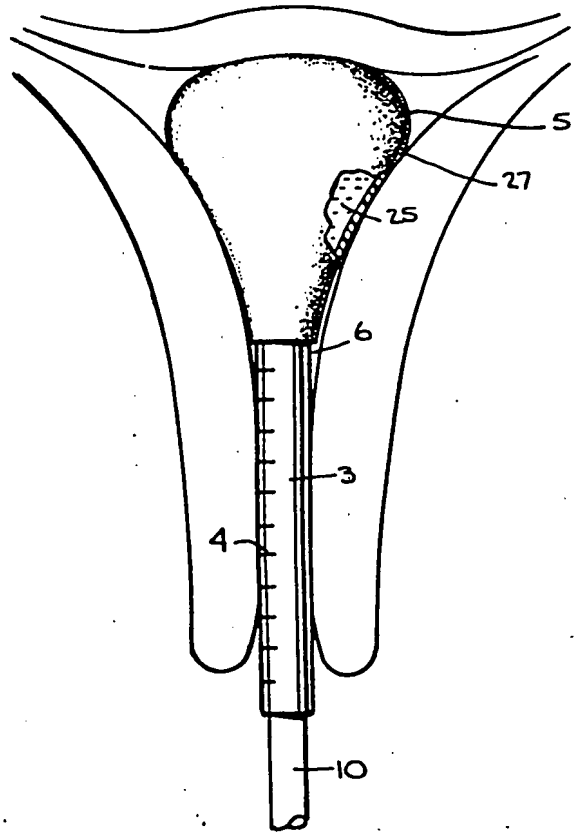
895046	12/1953	Fed. Rep. of Germany	128/401
287772	3/1928	United Kingdom .	
315971	7/1929	United Kingdom .	
317604	8/1929	United Kingdom .	

Primary Examiner—Max Hindenburg
Attorney, Agent, or Firm—Kenyon & Kenyon

[57] ABSTRACT

A method and apparatus for effecting necrosis of a tissue lining of a mammalian body cavity, particularly a uterine endometrium, by introducing an applicator comprising a distendable bladder connected to a catheter into the uterus, distending the bladder by introducing a non-toxic fluid under pressure, heating the fluid by means located internal to the bladder to a temperature of 190~ to 215~F. and preferably 210~F. for a period of 4 to 12 minutes and preferably 6 minutes and regulating said apparatus by means located external to the uterus, thereby cauterizing substantially the entirety of the tissue lining, particularly the endometrium.

3 Claims, 5 Drawing Sheets



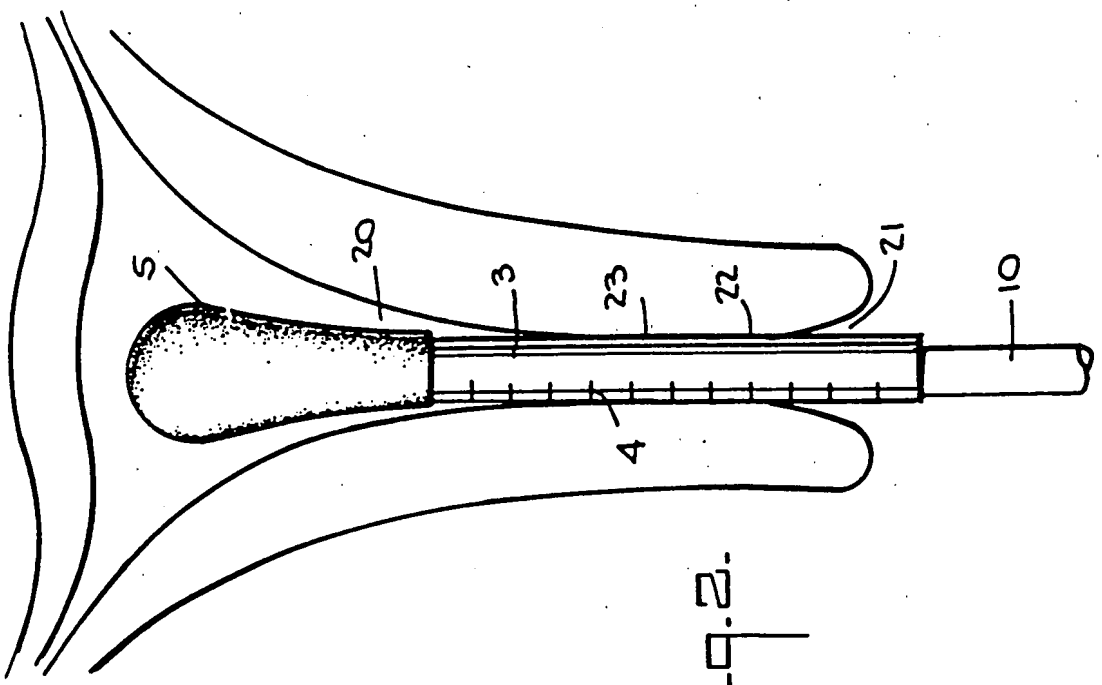


Fig. 2.

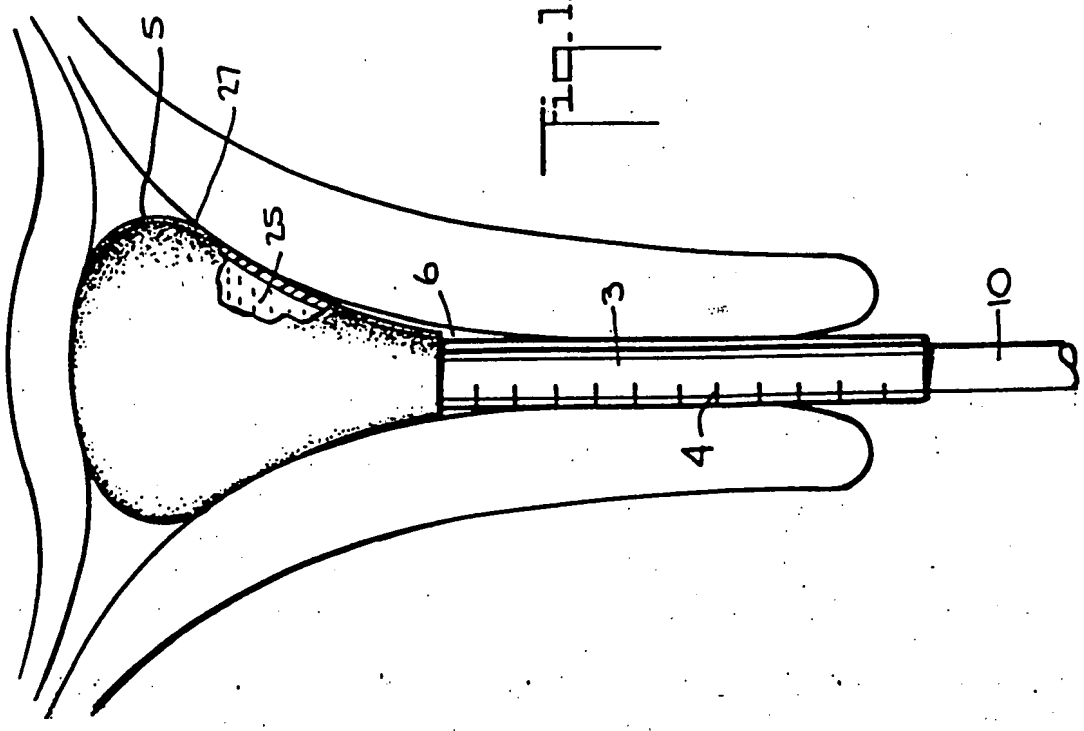


Fig. 1.

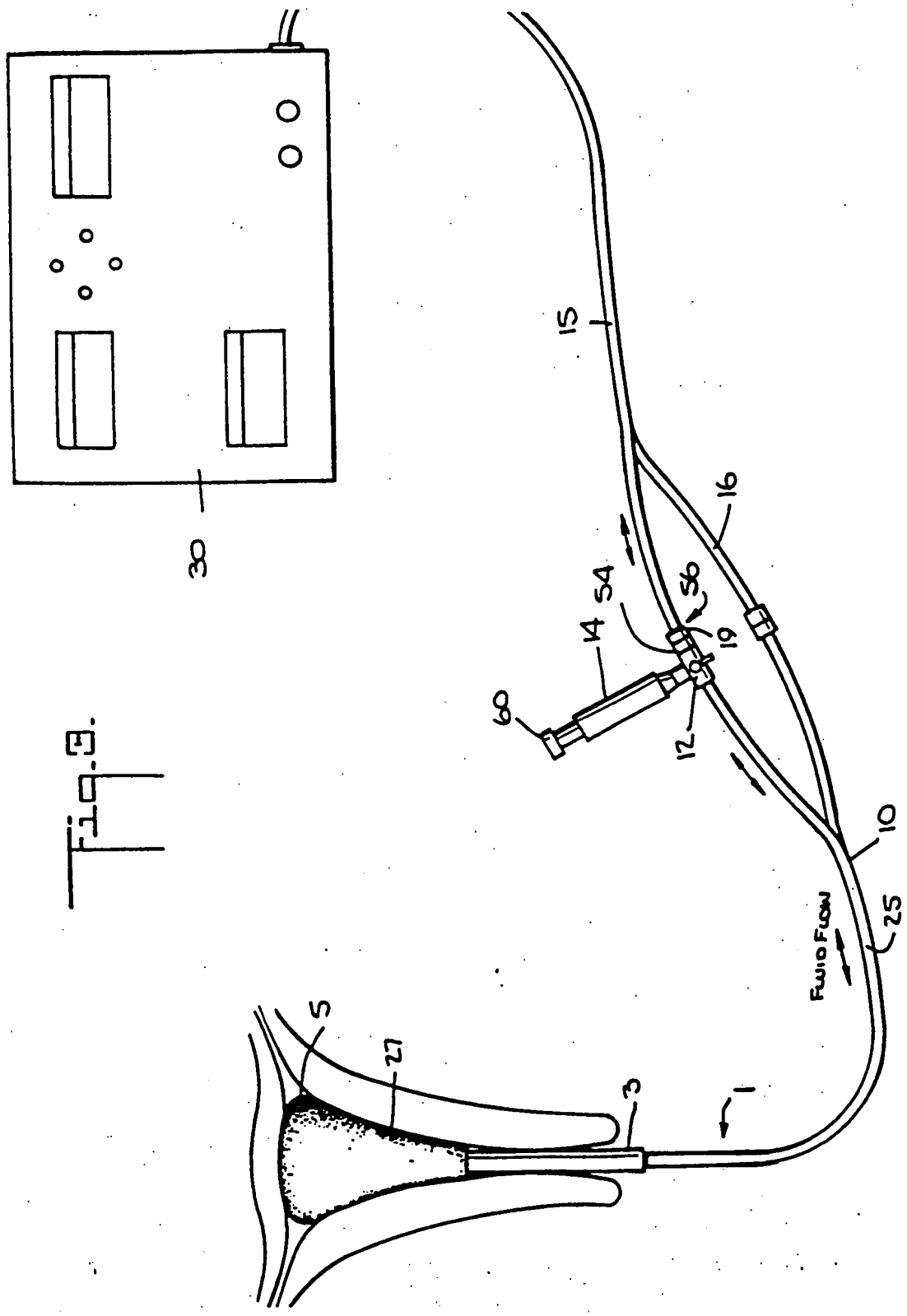
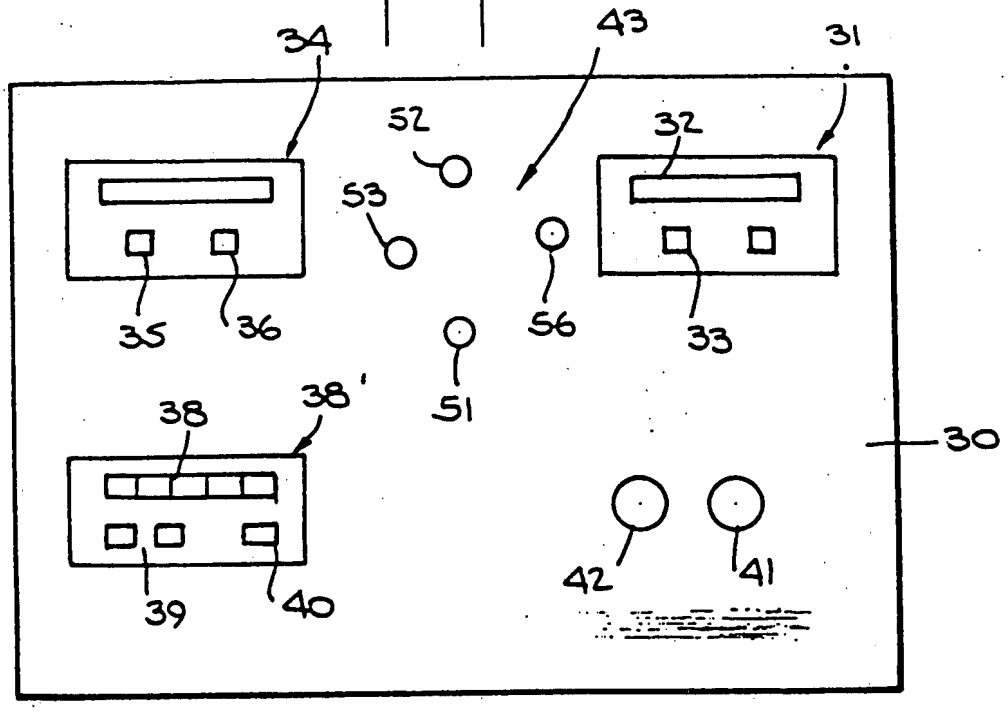


Fig. 3.

Fig. 4.


34
43
31
52
32
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56
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36
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41
39
40

Fig. 5.

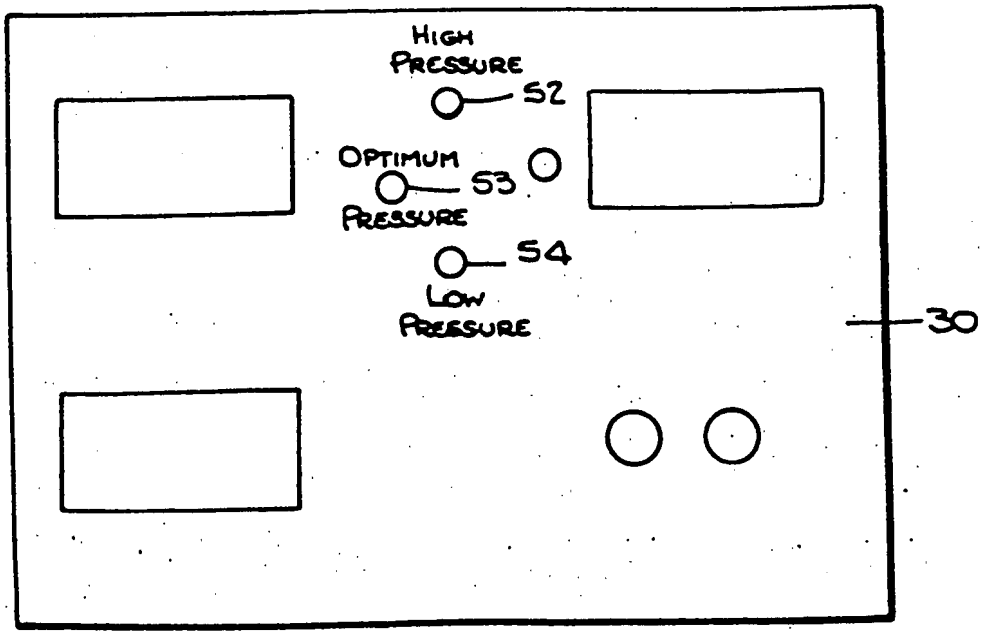

HIGH PRESSURE
52
OPTIMUM PRESSURE
53
54
LOW PRESSURE
30

Fig. 6A.

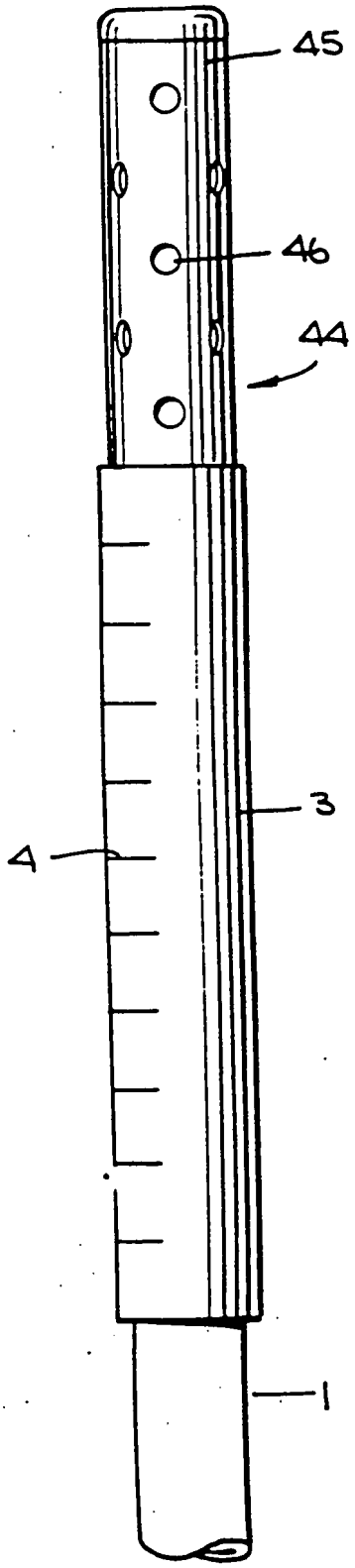
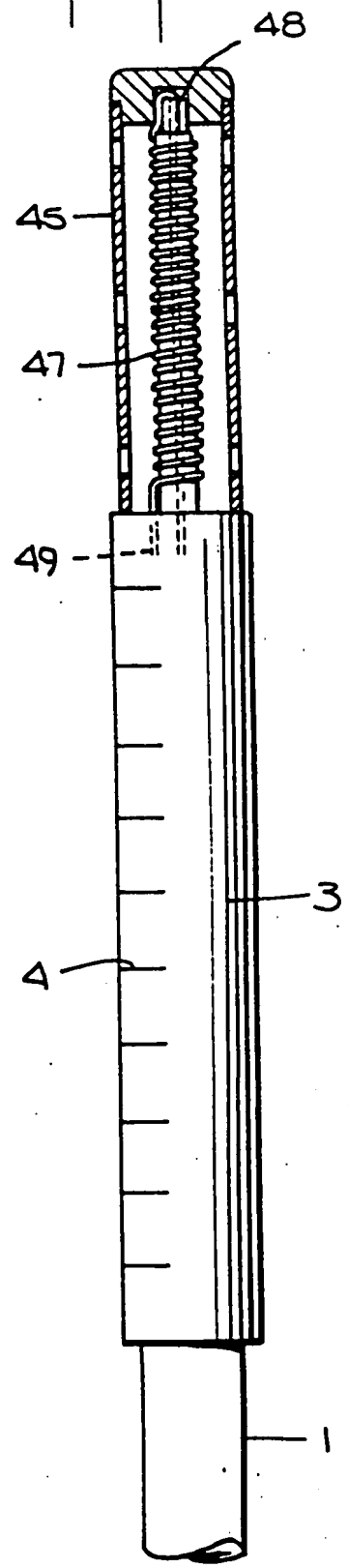


Fig. 6B.



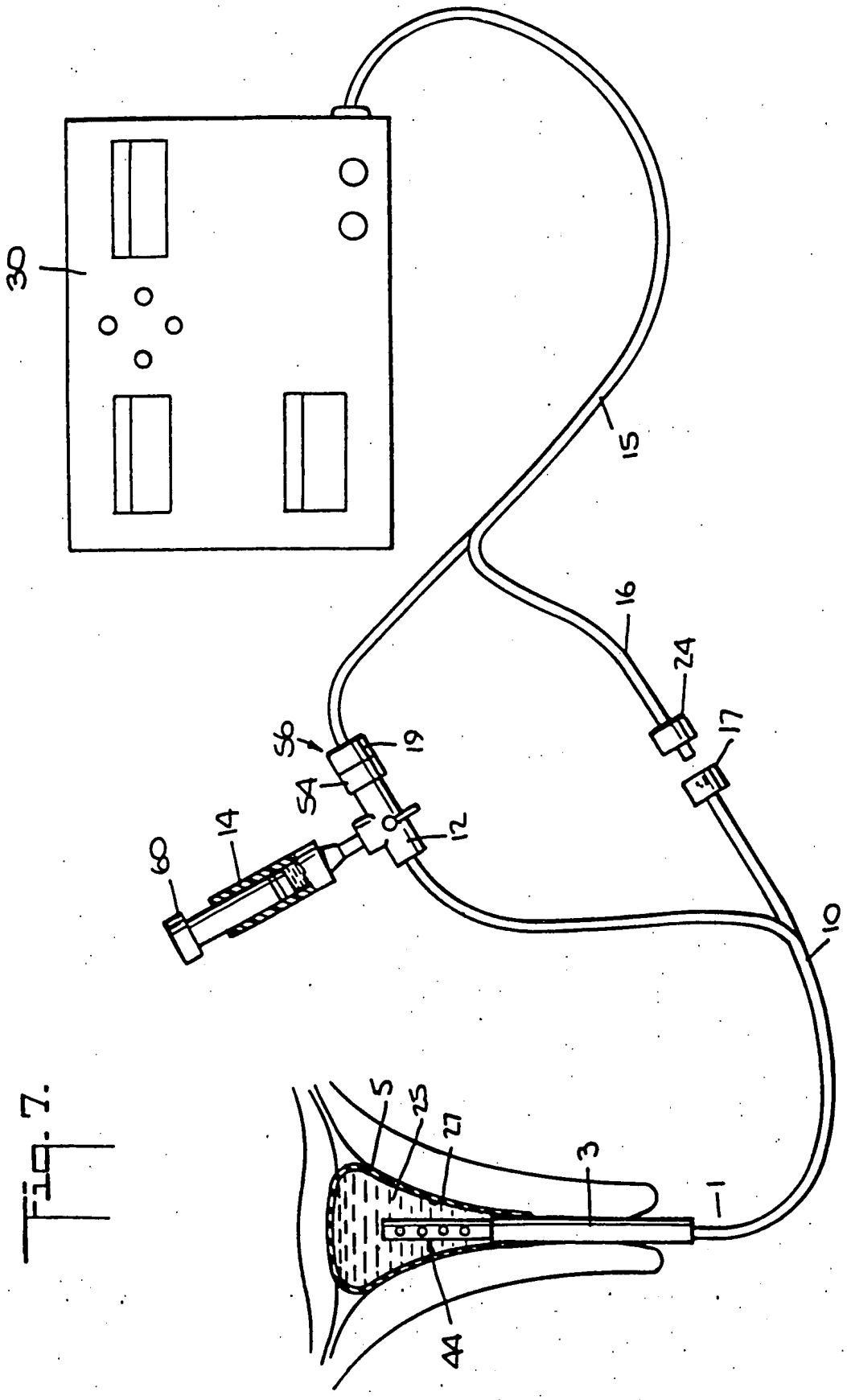


Fig. 7.

INTRAUTERINE CAUTERIZING METHOD

This is a division of application Ser. No. 07/242,730 filed Sept. 9, 1988, now U.S. Pat. No. 4,949,718.

BACKGROUND OF THE INVENTION

1. Field of the Invention

This invention relates to an apparatus and a method for cauterizing the tissue lining of a human body cavity, particularly the endometrium of the uterus. More specifically, the apparatus and method of the present invention ensures effective cauterization of the endometrium of a mammalian uterus without many of the disadvantages and dangerous features of known intrauterine cauterization techniques.

2. The Prior Art

The following terms as used herein have the meaning given below:

"Necrosis" means the death of cells in tissue.

"Endometrium" is that portion of the inner lining of the uterus to which an embryo normally attaches and excludes the portions of the uterine inner lining forming the cervix, to which the embryo usually does not attach.

Apparatus and methods for cauterization of the endometrium of a mammalian uterus, useful in sterilization procedures and cancer treatments, are well known. Thermal and cryogenic treatments have been utilized in such cauterization techniques and typically involve either the direct or indirect application of heat or cold to the tissue to be treated.

For example, a laser hysteroscope has been used to cauterize the endometrial layer of the uterus. This laser treatment suffers from several disadvantages. It requires the application of an intense amount of thermal energy to a relatively small area of tissue even though such a large amount of heat may not be necessary to effectively cauterize the tissue. Further, this laser treatment requires the physician to continually re-position the laser used in the treatment within the uterus in order to treat the entire endometrium. Such internal manipulation of a laser hysteroscope within the uterus of a patient is both difficult, requiring a significant level of skill to perform, and potentially dangerous. Accidental puncture of the uterine or tissue wall may result from manipulation of the laser scope within the uterus or body cavity, and tissue layers beneath the endometrium may be burned if a laser's beam is left focused on one area of tissue for too long a period of time.

A variety of alternatives to laser treatment in cauterizing the uterine endometrium are known. In U.S. Pat. No. 3,924,628, Droegemueller et al. disclose a method and apparatus for necrosing tissue cells that utilizes an extendable bladder which is inserted in the uterus and filled with a circulating fluid or gas at cryogenic temperatures (referring to temperatures sufficiently low to cause cell necrosis). The bladder disclosed by Droegemueller et al. is maintained in substantially continuous contact with the inner surface of the uterine lining and achieves necrosis of substantially all of the uterine endometrium in a single treatment. Droegemueller et al. disclose the use of liquid nitrogen that vaporizes prior to introduction into the bladder, thereby pressurizing the bladder to a level which ensures adequate contact with the uterus. Other fluids disclosed by Droegemueller et al. as useful in their method include refrigerants such as freon. Droegemueller et al.'s method and apparatus suffers from the disadvantage of employing cryogenic fluids which could prove toxic to a patient in the event of bladder rupture. Moreover, Droegemueller et al.'s apparatus does not allow regulating the pressure used to inflate the bladder. Another disadvantage of Droegemueler et al.'s technique is that cryogenic necrosis of the endometrium occurs at extremely low temperatures that pose a threat to tissue layers adjacent to the uterine endometrium. Droegemueller et al. and similar cryogenic techniques also require the use of expensive equipment such as compressors and insulated vessels associated with the storage and transmission of refrigerants. Moreover, Droegemueller et al.'s technique may require warming of the bladder in order to remove it from the body and minimize tearing of the surrounding tissue which has adhered to the bladder during the freezing process.

In U.S. Pat. No. 2,734,508, Kozinski discloses a therapeutic apparatus for applying dry heat to body cavities comprising an applicator that is introduced in the body cavity while deflated and which is subsequently inflated and heated by means of circulating hot air. Kozinski does not disclose an applicator which conforms to the shape of a body cavity. Further, given the lower heat transfer coefficients of gases as compared with liquid, treatment with Kozinski's apparatus should involve a long period of time in order to achieve necrosis, thereby exposing the patient to additional discomfort and risk. Moreover, Kozinski's apparatus does not provide for measurement and regulation of internal pressures and temperatures of the applicator introduced.

U.S. Pat. No. 2,077,453, issued to Albright, discloses a therapeutic appliance comprising a relatively long tubular applicator which is shaped and formed generally to the passage into which it is to be inserted and which has relatively thin elastic rubber walls that transfer heat and which distend to fit irregularities of the treated areas upon application of internal pressure. Albright also discloses that fluids such as heated water could be utilized as a heating means in his applicator. The applicator of Albright, like that of Kozinski, however, suffers from the disadvantage that the distension of its walls to conform to the irregularities of the endometrium is limited as Albright provides an integral rubber web which serves to prevent undue distension of the applicator. Moreover, Albright requires that the fluid be circulated throughout the apparatus. Albright also does not provide an apparatus that allows regulation of temperature and pressure of the fluid or other bladder inflation means.

U.S. Pat. No. 3,369,549, issued to Armao, discloses a therapeutic device for applying heat or cold to body cavities comprising a capsule probe containing a heat exchanger and a flexible bladder that can be inflated to conform to a body cavity. Armao does not, however, disclose a control means for regulating the temperature and pressure of the flexible applicator, nor does he disclose cauterizing tissue in the cavity being treated.

Other patents that disclose the use of thermal treatment of the interior lining of a body cavity include U.S. Pat. Nos. 2,192,768; 2,466,042; 2,777,445; and 3,369,549.

SUMMARY AND OBJECTS OF THE INVENTION

It is an object of the present invention to provide a safe and efficacious method for cauterizing the tissue lining of a body cavity, particularly the endometrium of a uterus.

It is another object of the present invention to provide a relatively inexpensive and easy to replace applicator heated by a nontoxic fluid that can be used to effect cauterization of the uterine endometrium and which is controlled by means external to the applicator.

It is another object of the present invention to provide a non-fluid circulating apparatus for heating a fluid while it is in a bladder within the uterus and for introducing the fluid under pressure into the bladder so as to assure substantially uniform contact of the bladder with the endometrium.

It is still another object of the present invention to provide an apparatus for regulating the temperature and pressure of the fluid in the bladder while the bladder is within the uterus.

The present invention provides a method for effecting cauterization necrosis of the tissue lining of a mammalian body cavity comprising the steps of inserting a distendable bladder into the body cavity; inflating said distendable bladder to a predetermined pressure with a fluid so that said distendable bladder is in contact with substantially all of the tissue lining for which necrosis is desired; heating said fluid by means of a heating element positioned internal to said distendable bladder; controlling the temperature and pressure of said fluid by control means connected to said distendable bladder; and maintaining said bladder so inflated with said fluid at a temperature for a period of time sufficient to effect cauterization necrosis of substantially all of the tissue lining of the body cavity for which necrosis is desired.

The present invention also provides a method for effecting cauterization necrosis of an uterine endometrium comprising the steps of inserting a distendable bladder into the uterus; inflating said distendable bladder to a predetermined pressure with a fluid so that said distendable bladder is in contact with substantially all of the endometrium; heating said fluid by means of a heating element positioned internal to said distendable bladder; regulating the temperature and pressure of said fluid by control means connected to said distendable bladder; and maintaining said bladder so inflated with said fluid at a temperature for a period of time sufficient to effect cauterization necrosis of substantially all of the uterine endometrium.

The present invention further provides a method for cauterizing substantially the entirety of the endometrium of a mammalian uterus by application within an inflatable bladder of a fluid at a pressure of 40 to 140 mmHg and preferably about 75 mmHg, heated to a temperature of 140~ to 215~F. and preferably about 210~F. for a period of 4 to 12 minutes, with a preference of around 6 minutes, thereby realizing substantial necrosis of substantially all of the uterine endometrium without significant damage to surrounding tissue.

The present invention also provides an apparatus for effecting necrosis of the tissue lining of a body cavity, and, in particular, substantially the entirety of the endometrium of a mammalian uterus comprising an applicator which comprises a catheter for insertion into the uterus, said catheter having a proximal end and a distal end, and a distendable bladder attached to said proximal end; inflating means connected to said distal end for distending said distendable bladder; heating means positioned internal to said distendable bladder for heating said distendable bladder; and control means for regulating the distending and heating of said distendable bladder.

The present invention provides an apparatus for effecting cauterization necrosis of the tissue lining of a body cavity, and in particular, substantially the entirety of the endometrium of a mammalian uterine comprising means for contacting the endometrium with an applicator comprising an inflatable bladder mounted on a length of rigid tubing attached to a length of flexible tubing; means for positioning the bladder in the uterus; means for distending the inflatable bladder, so as to assure substantially uniform contact with the endometrium, by introduction of a fluid under pressure into the applicator from a fluid source positioned external to the uterus; means for heating the bladder, comprising heating the fluid by a heating element positioned internal to the bladder; control means positioned external to the uterus and connected to the applicator by the flexible tubing and at least one wire connected to the heating element for regulating the distending and heating of the bladder; and means for disengaging the applicator from the control means so as to separate the applicator from the control means.

These and other objects of the present invention are achieved by a method in which necrosis of the endometrium of a mammalian uterus may be achieved by insertion of an applicator comprising rigid and flexible tubing and a readily distendable high strength bladder material into the uterus; introduction of a fluid through the tubing into the distendable bladder at a pressure of 40 to 140 mmHg and preferably about 75 mmHg, thereby inflating the bladder so that it substantially conforms to the irregularities in the shape of the endometrium; the pressure of the fluid measured and regulated by means external to the uterus; heating the fluid to a temperature of 140~ to 215~F. and preferably about 210~F., for a period of 4 to 12 minutes, with a preference of around 6 minutes, by heating means positioned within the distendable bladder and regulated by control means external to the applicator, thereby cauterizing substantially the entirety of the uterine endometrium.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 depicts a distendable bladder utilized in the method of the present invention which has been inserted into and inflated within a mammalian uterus.

FIG. 2 depicts placement of the distendable bladder within a mammalian uterus.

FIG. 3 is a view of an apparatus constructed in accordance with the invention that illustrates the applicator connections

FIG. 4 depicts a system control unit.

FIG. 5 is a detail view of a pressure limiting and safety monitor.

FIG. 6A is the vented heating element shield utilized in the method of the present invention.

FIG. 6B is a cutaway view of the vented heating element shield showing the heating element and thermocouple.

FIG. 7 depicts a means for connecting and disconnecting the applicator.

DESCRIPTION OF A PREFERRED EMBODIMENT

FIG. 1 shows an inflated distendable bladder 5 attached to rigid tubing 3 located within a human uterus 6. Inflation of the distendable bladder 5 with a fluid 25 assures uniform contact of the bladder with the endometrial tissue layer 27 of mammalian uterus 6.

The rigid tubing 3 and the attached distendable bladder 5 must be sufficiently small, when the distendable bladder is deflated, so that it can be conveniently and safely inserted into the uterus 6 through a partially dilated cervix 22. The rigid tubing with the deflated bladder is aligned with the cervical canal after the cervix is exposed with a speculum and grasped with a tenaculum. After the distendable bladder 5 has been inserted, the distendable bladder 5 should be inflated to a pressure sufficient to ensure firm contact with the tissue to be necrosed, in this case the endometrial tissue layer on the interior uterine surface, but should preferably be maintained at or about 40 to 140 mmHg, and preferably about 75 mmHg, to minimize risk of rupture of the distendable bladder 5 and possible internal injury to the patient.

Distendable bladder 5 must be capable of withstanding high temperatures without rupturing, and preferably have as good a heat transfer characteristic as is obtainable in such materials to provide efficient heating action. A distendable bladder of a heat curing rubber such as latex has been found satisfactory.

Fluid 25 preferably should be a sterile non-toxic fluid with a boiling point of at least 212~F. A five percent dextrose in water solution has been found satisfactory.

As illustrated in FIG. 2, the uninflated distendable bladder 5 attached to rigid tubing 3 is inserted into the vagina 21, past the cervical os 22, through the cervical canal 23, for placement in the uterine cavity 20. Placement may be aided by virtue of scale gradations 4 located on the rigid tubing 3 to indicate the depth of insertion of the bladder 5. Rigid tubing 3 is attached to a control unit 30 (shown in FIG. 3) via flexible tubing 10.

FIG. 3 depicts the arrangement of control unit 30 and applicator end 1, comprising the distendable bladder 5, rigid tubing 3 and flexible tubing 10, and the interconnection of those elements. A fluid system 55 comprises that portion of the invention through which the fluid 25 travels, including a hypodermic barrel 14 or other fluid source (not shown), flexible tubing 10, rigid tubing 3, distendable bladder 5 and control unit 30. Manipulation of the hypodermic barrel 14 enables the operator of the system to control the amount of fluid 25 in the fluid system 55, inflation and deflation of the distendable bladder by adding or removing fluid, respectively, and pressure of the fluid 25 in the system. Hypodermic barrel 14 also provides protection for the patient by allowing fast and safe reduction of excessive pressures in the system that might build up through some malfunction.

Manipulation of the hypodermic barrel 14 by depressing a plunger 60 causes fluid 25 to be introduced through 3-way stopcock 12 into the flexible tubing 10, and to the rigid tubing 3. The fluid 25 emerges from rigid tubing 3 and into distendable bladder 5, forcing distendable bladder 5 to expand into contact with the endometrial tissue layer 27 of the uterus 6. The fluid 25 is also directed along the flexible tubing to the control unit 30 allowing measurement of the fluid pressure within the bladder by well known means.

Each of the parts of the fluid system 55 is in fluid communication providing constant fluid pressure within the entire fluid system 55 and allowing measurement of the pressure at the applicator end 1 via measurement of pressure of the end attached to the control unit 30.

Control unit 30 is connected to applicator end 1 via plastic sheath 15 which contains flexible tubing 10 and electrical sheath 16. Flexible tubing 10 is connected to a fluid joint 56 via pressure transducer 54, by well known means. Using a standard luer lock connector 19, pressure transducer 54 and hypodermic barrel 14 are connected to flexible tubing 10 via a readily available 3-way stopcock 12. 3-way stopcock 12 may be used to isolate the hypodermic barrel 14 or other fluid source from the fluid system 55 once the desired fluid pressure is reached.

FIG. 4 depicts control unit 30, consisting of fluid temperature control 31, fluid pressure control 34, time control 38' and a power source (not shown). The control unit 30 includes a power switch 42 and fuse 41. Fluid temperature is regulated by fluid temperature control 31 and is set by temperature set/reset button 33. The temperature of fluid 25 in the distendable applicator 5 is shown at temperature display 32.

Fluid pressure within the fluid system 55 is regulated by means of controls located on fluid pressure control panel 34. The upper limit for fluid pressure is controlled by high pressure set/reset button 35, with the lower limit controlled by low pressure set/reset button 36. Fluid pressure in mmHg is shown by LED pressure display 37. Control unit 30 also has pressure indicator display 43, which upon introduction of fluid 25 into the fluid system 55 provides an easy to see visual display of fluid pressure within the fluid system 55.

Time for the procedure is shown at time display 38, which displays both lapsed time and time remaining for the procedure. Total time for the procedure may be easily set in minutes, seconds, and tenths of seconds using time set buttons 39 and may be cleared or reset using time clear/reset button 40.

A simplified means for determining whether the fluid 25 is within the preset pressure range is depicted in FIG. 5, which illustrates the pressure indicator display 43. The pressure indicator display 43 is comprised of a low pressure indicator 51, a high pressure indicator 52 and an optimum pressure indicator 53. As fluid 25 is introduced into the fluid system 55 by manipulation of hypodermic barrel 13, the pressure indicator display 43 is successively illuminated as various fluid pressures are reached. Low pressure indicator 51 is illuminated when fluid pressure is below the preset range. High pressure indicator 52 is illuminated when fluid pressure is above the preset range. Optimum pressure indicator 53 is illuminated when fluid pressure is within the preset range.

These indicators allow the practitioner to readily reach the preset pressure range by varying the amount of fluid in the fluid system via manipulation of the hypodermic barrel 14. A separate heating element indicator 55 is also provided to indicate when power is being provided to a heating element 44 located within the distendable applicator 5.

Two views of heating element 44 are shown in FIGS. 6A and 6B. FIG. 6A is an external view of heating element 44, which comprises heating element coil shield 45 and ventilation holes 46.

FIG. 6B is a cutaway view of heating element 44, wherein wire leads 49 provide power from system control unit 30 to heating element coil 47 causing heating element coil 47 to heat the fluid 25 which comes into contact with the heating element coil 47 as the fluid 25 flows through the ventilation holes 46. Temperature of the fluid 25 is measured by thermocouple 48 and is displayed at temperature display 32. Heat element coil shield 45 prevents distendable bladder 5 from contacting the heating element coil 47.

The applicator end 1 is designed to be easy to replace as shown in FIG. 7, which depicts control unit end 30' and applicator end 1 of the invention. Control unit end 30' is composed of electrical sheath 16 which is attached on one end to control unit 30 and on the other end to male electrical connector 24, which allows transmittal of power to the heating element 44. Male electrical connector 24 is readily attached or disattached to female electrical connector 17 on the applicator end 1.

Control unit end 30' is also comprised of components from the fluid system 55, including flexible tubing 10 attached to 3-way stopcock 12. 3-way stopcock 12 provides control over the introduction and removal of fluid 25 via hypodermic barrel 14. The applicator end 1 is easily connected or disconnected from the 3-way stopcock via a luer lock connector 19 attached to pressure transducer 54.

The invention will now be illustrated by the following example.

Example

The cauterization procedure is preceded by screening against cancer of the affected region and physical condition within established norms. A PAP smear and endometrial biopsy/curettage must exclude cancer or precancerous lesions of the uterus and cervix. If a fibroid uterus is present, an ultrasound should exclude ovarian masses. The uterine cavity must be 10 cm or less in length to be suitable for the small distendable bladder size.

The patient should be post menstrual or start on Danazol, or the equivalent which causes reduction in bleeding and a thin endometrium, at a rate of 800 ml daily, from the 5th day of the previous menstrual period until two weeks after the procedure. She will undergo the procedure in the ambulatory surgery unit or outpatient facility where Valium and/or Demerol can be given intravenously if there is pain during the heating phase of the procedure.

The applicator will be inserted after a bimanual examination and speculum of the cervix. Dilation to 6 mm. may be required which may necessitate a local 1% lidocane block of the cervix. Once in place the applicator stem protrudes from the vagina and consists of an electrical connecting plug and rigid tubing. Placement of the applicator may be facilitated by distance markings on the rigid tubing indicating depth of insertion.

Upon placement of the applicator it will be connected to a control unit via attachment of the electrical connector and flexible tubing attached to the rigid tubing to their counterparts extending from the control unit.

Subsequent to insertion of the applicator, the control unit will be powered on in order to allow the practitioner to set the system constraints. The temperature of the fluid in the bladder will be set at the temperature control panel and can be measured via the thermocouple located within the bladder. Fluid pressure constraints are set at the pressure control panel, and upon inflation of the distendable bladder by introduction of fluid to the fluid system by depressing the plunger on the hypodermic barrel, can be easily measured by looking at the pressure indicator lights located on the control unit.

The practitioner then proceeds to inflate the distendable bladder by rotating the lever on the 3-way stopcock in order to access the fluid source and depressing the plunger on the hypodermic barrel which may serve as the fluid source. The practitioner injects the fluid into the fluid system until the pressure indicator lights indicate that the fluid pressure is within the pre-set constraints. At that point, the practitioner manipulates the 3-way stopcock to close off access to the fluid system by the fluid remaining in the hypodermic barrel. Thus, the fluid is non-circulating during the heating portion of the procedure, in part allowing more precise measurement of fluid temperature. The volume of fluid necessary to inflate the bladder will vary from 3 to 20 ml in most cases in order to reach the pressure wherein the bladder is substantially in contact with all of the endometrium.

The practitioner then turns on the heating element in order to heat the fluid to a pre-set level. The heating element in the bladder is connected via the plug to a 12 volt system which will bring the fluid in the bladder to the level of boiling as needed for each particular local, i.e. 190 degrees farenheit in Mexico City, and 212 degrees farenheit in New York City. Once that temperature level is reached, the system timer is activated to time the procedure and provide automatic turn off of the heating element at the end of a pre-set period.

Upon completion of the procedure, the 3-way stopcock is again manipulated to allow the fluid to be withdrawn from the fluid system causing the distendable bladder to deflate. Upon deflation of the distendable bladder, the applicator may be safely withdrawn from the patient. The coagulated endometrium is then removed from the endometrial cavity with a curette, leaving the underlying surface free to form adhesions with the other opposing surfaces of the endometrial cavity.

What is claimed is:

1. A method for effecting cauterization necrosis of the tissue lining of a mammalian body cavity comprising the steps of:
   (a) inserting a distendable bladder into the body cavity;
   (b) inflating said distendable bladder to a predetermined pressure with a fluid so that said distendable bladder is in contact with substantially all of the tissue lining for which necrosis is desired;
   (c) heating said fluid by means of a heating element positioned internal to said distendable bladder;
   (d) controlling the temperature and pressure of said fluid by control means connected to said distendable bladder; and
   (e) maintaining the exterior of said bladder so inflated with said fluid at a temperature of about 190° F. to about 215° F. and preferably about 210° F. for a period of time of from about 4 to about 12 minutes, and preferably about 6 minutes to effect cauterization necrosis of substantially all of the tissue lining of the body cavity for which necrosis is desired.

2. A method for effecting cauterization necrosis of an uterine endometrium comprising the steps of:
   (a) inserting a distendable bladder into the uterus;
   (b) inflating said distendable bladder to a predetermined pressure with a fluid so that said distendable bladder is in contact with substantially all of the endometrium;
   (c) heating said fluid by means of a heating element positioned internal to said distendable bladder;
   (d) regulating the temperature and pressure of said fluid by control means connected to said distendable bladder; and
   (e) maintaining said bladder so inflated with said fluid at a temperature for a period of time sufficient to effect cauterization necrosis of substantially all of the uterine endometrium.

3. A method as described in claim 2, wherein the exterior of said distendable bladder in contact with the endometrium is maintained at a temperature of 190~ to 215~F. and preferably about 210~F. for a period of time of from 4 to 12 minutes, and preferably around 6 minutes.

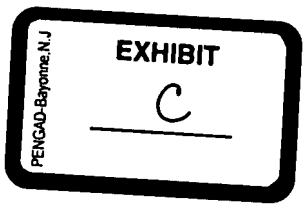
* * * * *

A. IDE No. G940155 - Submissions to FDA and Responses Through FDA Approval.

10/28/94	IDE application submitted to FDA by Gynecare, Inc.
11/02/94	FDA Notice of IDE No. G940155 assigned for EASY(TM) ENDOMETRIAL ABLATION SYSTEM (effective November 30, 1994).
09/05/95	Amendment to IDE No. G940155 submitted for performing efficacy study of the Gynecare Uterine Balloon Therapy (UBT) System in comparison with Rollerball Endometrial Ablation.
09/25/95	Supplemental Application submitted to IDE No. G940155 updating sections of revised protocol in response to September 21, 1995, conference call of Mr. Pollard of the FDA.
10/02/95	Supplemental application submitted to update "Other Institutions" section of IDE No. G940155.
10/05/95	Response of FDA granting conditional approval of efficacy and safety clinical study for the UBT.
02/23/96	Response of FDA approving proposed investigational plan and protocol changes.
03/31/97	Pre-PMA submission for ThermaChoice™ Uterine Balloon Therapy (UBT) System.

B. PMA No. 970016 - Submissions to FDA and Responses Through FDA Approval.

05/21/97	Fax inquiry and comments from FDA concerning outstanding issues on preliminary review of PrePMA submission of 03/31/97.
06/16/97	Formal premarketing approval (PMA) application submitted by Gynecare, Inc. for ThermaChoice™ Uterine Balloon Therapy Device and response to FDA facsimile of 05/21/97.



08/11/97	PMA amendment submitted in response to FDA telephone calls of 08/08/97 concerning manufacturing instructions, quality assurance procedures and testing matters.
08/29/97	PMA amendment submitting interim update Table of Contents.
10/06/97	Panel Hearing.
10/10/97	Post panel letter from FDA and notice of deficiency discussed in teleconference of 10/1/97.
10/16/97	Followup response to FDA teleconference of 10/16/97 concerning engineering tests and clinical aspects.
10/17/97	Response to deficiency set forth in 10/10/97 letter submitted.
10/20/97	Followup response to FDA teleconference of 10/08/97 concerning software validation issues in letter of 10/10/97.
10/21/97	Followup response to FDA teleconference of 10/21/97 concerning engineering test data sent 10/16/97.
10/31/97	PMA amendments submitted to comply with FDA panel conditions in status letter of 10/10/97.
11/25/97	Supplemental amendment notifying FDA of merger of Gynecare, Inc./Ethicon, Inc. on November 20, 1997.
12/10/97	Copy of final labeling changes submitted in response to FDA teleconference of 12/10/97.
12/12/97	PMA approved by FDA to Gynecare, Inc./Ethicon, Inc.
12/31/97	PMA amendments and submission of two copies of final labeling to comply with conditions of approval.

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Inventor:	Robert S. Neuwirth, et al.	) Assignee:	Gynelab Products, Inc.
Patent No.:	5,105,808	) Licensee:	Gynecare, Inc. Ethicon, Inc.
Issue Date:	April 21, 1992	)	
For:	INTRAUTERINE CAUTERIZING METHOD	)	

POWER OF ATTORNEY AND CERTIFICATE UNDER 37 CFR 3.73(b)

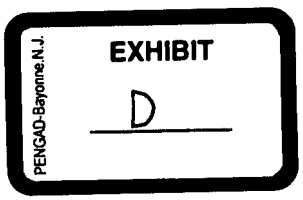
Assistant Commissioner for Patents
U.S. Patent and Trademark Office
Box Patent Ext.
Washington, D.C. 20231

Sir:

GYNELAB PRODUCTS, INC. certifies that it is the assignee of the entire right, title, and interest in the above-identified patent, which is a division of U.S. Patent No. 4,949,718, by virtue of an assignment recorded in the Patent Office Assignment Records, Reel 4961, Frames 0836- 0838, on September 9, 1988, and hereby appoints the following:

Michael A. Hierl	Reg. No. 29,807	Arne M. Olson	Reg. No. 30,203
Dolores T. Kenney	Reg. No. 31,269	Talivaldis Cepuritis	Reg. No. 20,818
John W. Klooster	Reg. No. 18,953	Seymour Rothstein	Reg. No. 19,369
Daniel J. Deneufbourg	Reg. No. 33,675	Eddie L. Bishop	Reg. No. 39,110
Steven D. Weseman	Reg. No. 41,372	Robert W. Diehl	Reg. No. 35,118

all of the firm of OLSON & OLSON & HIERL, LTD., both jointly and severally, as attorneys with full powers of substitution and revocation to transact all business in the United States Patent and Trademark Office with regard to requesting an extension of term for U.S. Patent No. 5,105,808 and matters related thereto.



Please direct all telephone calls and all correspondence relating to the above-identified matter to:

Talivaldis Cepuritis, Esq.
OLSON & HIERL, LTD.
20 North Wacker Drive
36th Floor
Chicago, Illinois 60606
(312) 580-1180
(312) 580-1189 (facsimile)

The undersigned (whose title is supplied below) is empowered to sign this certificate and power of attorney on behalf of the assignee.

GYNELAB PRODUCTS, INC.

Date: Feb 3, 1998

By: Lee R. Bolduc
Lee R. Bolduc - President

Gynelab Products, Inc.
36 Nashua Way
Ocala, Florida 34482
(352) 237-9820

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Inventor:	Robert S. Neuwirth, et al.	Assignee:	Gynelab Products, Inc.
Patent No.:	5,105,808	Licensee:	Gynecare, Inc./Ethicon, Inc.
Issue Date:	April 21, 1992		
For:	INTRAUTERINE CAUTERIZING METHOD		

AUTHORIZATION OF PRE-MARKETING APPROVAL HOLDER

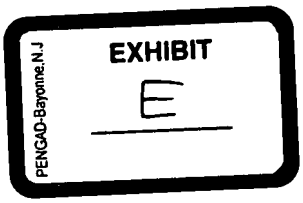
Assistant Commissioner for Patents
U.S. Patent and Trademark Office
Box Patent Ext.
Washington, D.C. 20231

Sir:

Gynecare, Inc./Ethicon, Inc., is the exclusive licensee of Gynelab Products, Inc., is the holder of the pre-marketing approval of the device for practicing the method that is the subject of U.S. Patent No. 5,105,808, which is a division of U.S. Patent No. 4,949,718 and hereby states that Gynelab Products, Inc., the requestor for patent term extension, is authorized to rely on the pre-marketing activities of Gynecare, Inc./Ethicon, Inc. in requesting an extension of term for U.S. Patent No. 5,105,808, issued to Neuwirth et al, and matters related thereto. Gynecare, Inc. has been acquired by Ethicon, Inc. and is now a wholly owned subsidiary of Ethicon, Inc.

Please direct all correspondence regarding the request for extension of term to Gynelab Products, Inc. at the following address:

Talivaldis Cepuritis, Esq.
OLSON & HIERL, LTD.
20 North Wacker Drive, 36th Floor
Chicago, Illinois 60606
(312) 580-1180
(312) 580-1189 (facsimile)



Ethicon, Inc.

Date: February 2, , 1998

By: Howard Zauberman
Howard Zauberman, Vice President,
New Business Development & Technology

DATE: 7-15-08 APPLICATION NUMBER: 07/565,154

DOC CODE: TERM.PTD.LTR DOC DATE: 4-7-98

DELIVER THE ATTACHED FILE/DOCUMENT TO THE TC SCANNIG CENETER

CONTRACTOR: THE ATTACHED FILE/DOCUMENT MUST BE INDEXED AND SCANNED INTO IFW WITHIN 8 WORK HOURS; UPLOADING OF THE SCANNED IMAGES SHOULD OCCUR NO LATER THAN 16 WORK HOURS FOLLOWING RECEIPT OF THIS REQUEST

AFTER SCANNING, ORIGINAL DOCUMENTS SHOULD BE BOXED IN ACCORDANCE WITH INSTRUCTIONS

APR - 7 1998

UNITED STATES DEPARTMENT OF COMMERCE
Patent and Trademark Office
ASSISTANT SECRETARY AND COMMISSIONER
OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

Ronald L. Wilson, Director
Health Assessment Policy Staff
Office of Health Affairs (HFY-20)
Food and Drug Administration
5600 Fishers Lane, Room 15-22
Rockville, MD 20857

Dear Mr. Wilson:

The attached application for patent term extension of U.S. Patent No. 5,105,808 was filed on February 6, 1998, under 35 U.S.C. § 156.

The assistance of your Office is requested in confirming that the product identified in the application, ThermaChoice™ Uterine Balloon Therapy System, has been subject to a regulatory review period within the meaning of 35 U.S.C. § 156(g) before its first commercial marketing or use and that the application for patent term extension was filed within the sixty-day period after the product was approved. Since a determination has not been made whether the patent in question claims a product which has been subject to the Federal Food, Drug and Cosmetic Act, this communication is NOT to be considered as notice which may be made in the future pursuant to 35 U.S.C. § 156(d)(2)(A).

Our review of the application to date indicates that the subject patent would be eligible for extension of the patent term under 35 U.S.C. § 156.

Inquiries regarding this communication should be directed to the undersigned at (703) 306-3159 (telephone) or (703)308-6916 (facsimile).

Karin Tyson
Legal Advisor
Special Program Law Office
Office of the Deputy Assistant Commissioner
for Patent Policy and Projects

cc: OLSON & HIERL, LTD
20 NORTH WACKER DRIVE
36TH FLOOR
CHICAGO IL 60606

kt

DATE: 7-15-08 APPLICATION NUMBER: 07/565154

DOC CODE: TERM.AGC.LET DOC DATE: 12-21-98

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AFTER SCANNING, ORIGINAL DOCUMENTS SHOULD BE BOXED IN ACCORDANCE WITH INSTRUCTIONS

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

DEC 17 1998

Re: Therma Choice™ Uterine Ballon Therapy System
Docket No. 98E-0485

Stephen G. Kunin
Deputy Assistant Commissioner for
Patent Policy and Projects
U.S. Patent and Trademark Office
Box Pat. Ext.
Assistant Commissioner for Patents
Washington, D.C. 20231

Dear Mr. Kunin:

This is in regard to the application for patent term extension for U.S. Patent No. 5,105,808 filed by Gynelab Products, Inc. under 35 U.S.C. § 156. The medical device claimed by the patent is Therma Choice™ Uterine Ballon Therapy System, which was assigned premarket approval application (PMA) No. P970021.

A review of the Food and Drug Administration's official records indicates that this product was subject to a regulatory review period before its commercial marketing or use, as required under 35 U.S.C. § 156(a)(4). Our records also indicate that it represents the first permitted commercial marketing or use of the product, as defined under 35 U.S.C. § 156(f)(1), and interpreted by the courts in Glaxo Operations UK Ltd. v. Quigg, 706 F. Supp. 1224 (E.D. Va. 1989), aff'd, 894 F. 2d 392 (Fed. Cir. 1990).

The PMA was approved on December 12, 1997, which makes the submission of the patent term extension application on February 6, 1998, timely within the meaning of 35 U.S.C. § 156(d)(1).

Should you conclude that the subject patent is eligible for patent term extension, please advise us accordingly. As required by 35 U.S.C. § 156(d)(2)(A) we will then determine the applicable regulatory review period, publish the determination in the Federal Register, and notify you of our determination.

Please let me know if we can be of further assistance.

Sincerely yours,

Thomas J. McGinnis

Ronald L. Wilson, Director
Health Assessment Policy Staff
Office of Health Affairs

cc: Talivaldis Cepuritis
Olson & Hierl, Ltd.
36th Floor
20 North Wacker Drive
Chicago, IL 60606